US009463143B2

(12) **United States Patent**
Oates, II et al.

(10) **Patent No.: US 9,463,143 B2**
(45) **Date of Patent: Oct. 11, 2016**

(54) **APPARATUS AND METHODS FOR ORAL ADMINISTRATION OF FLUIDS AND MEDICAL INSTRUMENTATION**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **14/250,734**

(22) Filed: **Apr. 11, 2014**

(65) **Prior Publication Data**

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Related U.S. Application Data

(63) Continuation of application No. 14/062,736, filed on Oct. 24, 2013, now Pat. No. 8,945,182, which is a continuation-in-part of application No. PCT/US2013/037492, filed on Apr. 19, 2013.

(Continued)

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A61J 1/06 (2006.01)
A61J 17/00 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61J 17/00*** (2013.01); ***A61J 7/0053*** (2013.01); *A61J 17/006* (2015.05); *A61J 2015/008* (2013.01); *A61J 2017/006* (2013.01)

(58) **Field of Classification Search**
CPC A61J 1/05; A61J 1/067; A61J 7/0053; A61J 17/006; A61M 15/003; B65D 17/161; B65D 17/163; B65D 17/165; B65D 17/166; B65D 17/168
USPC 604/403; 206/528–540, 570, 571; 222/107, 541.6, 541.9; 383/207–209
See application file for complete search history.

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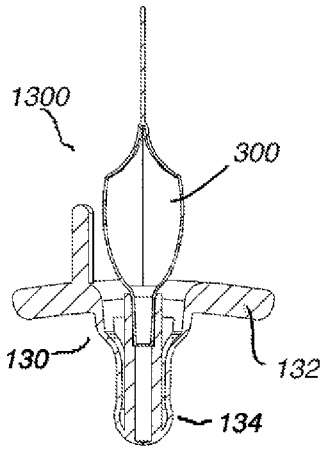
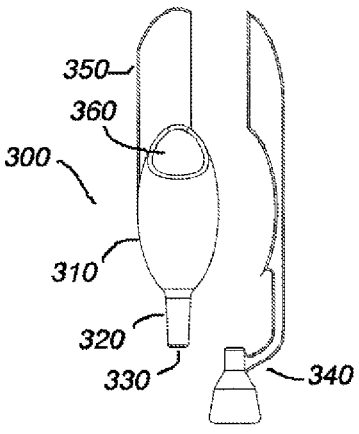
(57) **ABSTRACT**

Methods and devices for orally administering fluids and medical instrumentation to individuals for the promotion of health are disclosed. An apparatus is described comprising a pacifier configured to hold fluid and configured for sucking. In some embodiments, the apparatus includes a balloon positioned within a cavity of the pacifier. The balloon is configured to facilitate expulsion of the fluid from the cavity and to limit a user's ingestion of air. In other embodiments, the apparatus includes a cartridge or ampoule configured to store a fluid and expel the fluid through the pacifier. Systems are disclosed which include the pacifier apparatus, a known quantity of fluid or powder, and sterile packaging. Other systems are disclosed whereby various attachments, both medical and non-medical, couple to the apparatus. Methods of using and methods of manufacturing are also disclosed.

29 Claims, 32 Drawing Sheets





Related U.S. Application Data

(60) Provisional application No. 61/636,401, filed on Apr. 20, 2012, provisional application No. 61/659,360, filed on Jun. 13, 2012, provisional application No. 61/709,053, filed on Oct. 2, 2012, provisional application No. 61/802,141, filed on Mar. 15, 2013.

(51) **Int. Cl.**

A61J 7/00	(2006.01)
A61J 15/00	(2006.01)

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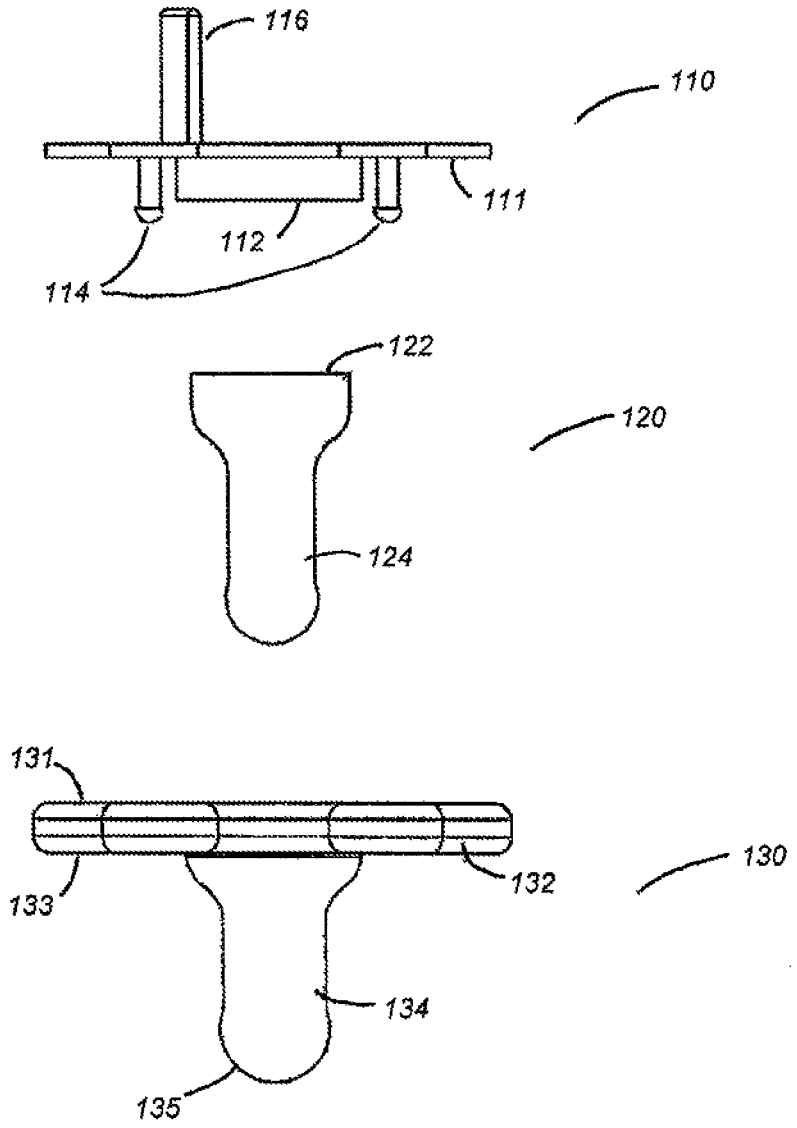

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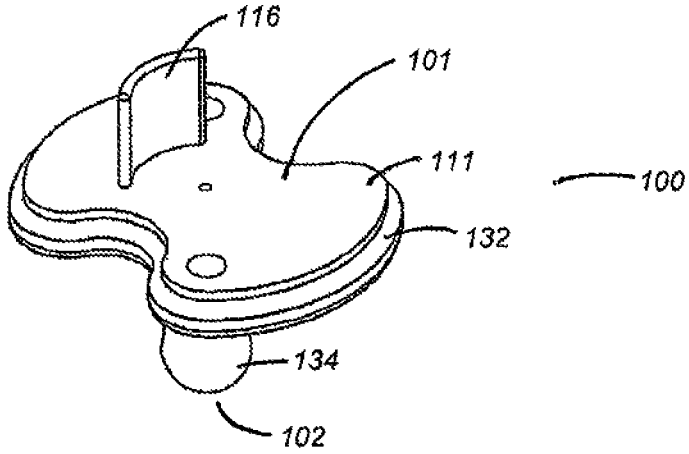

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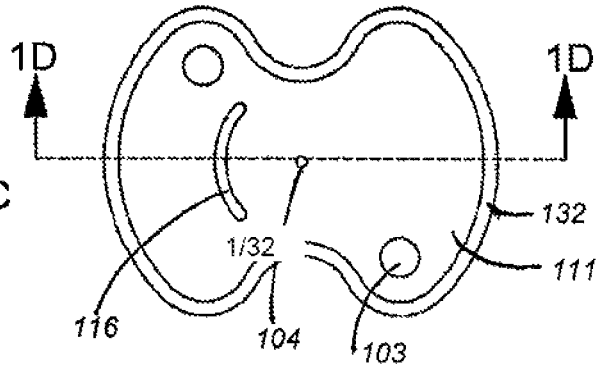

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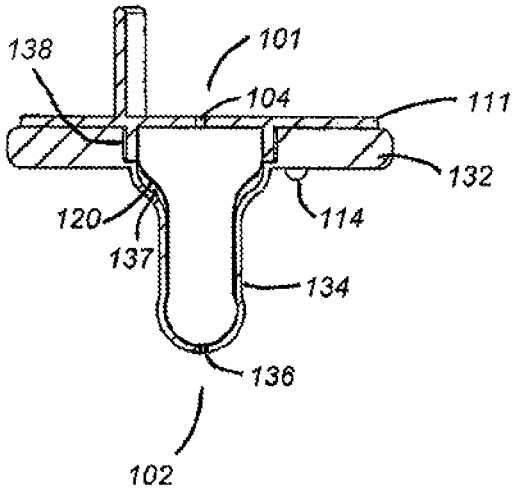

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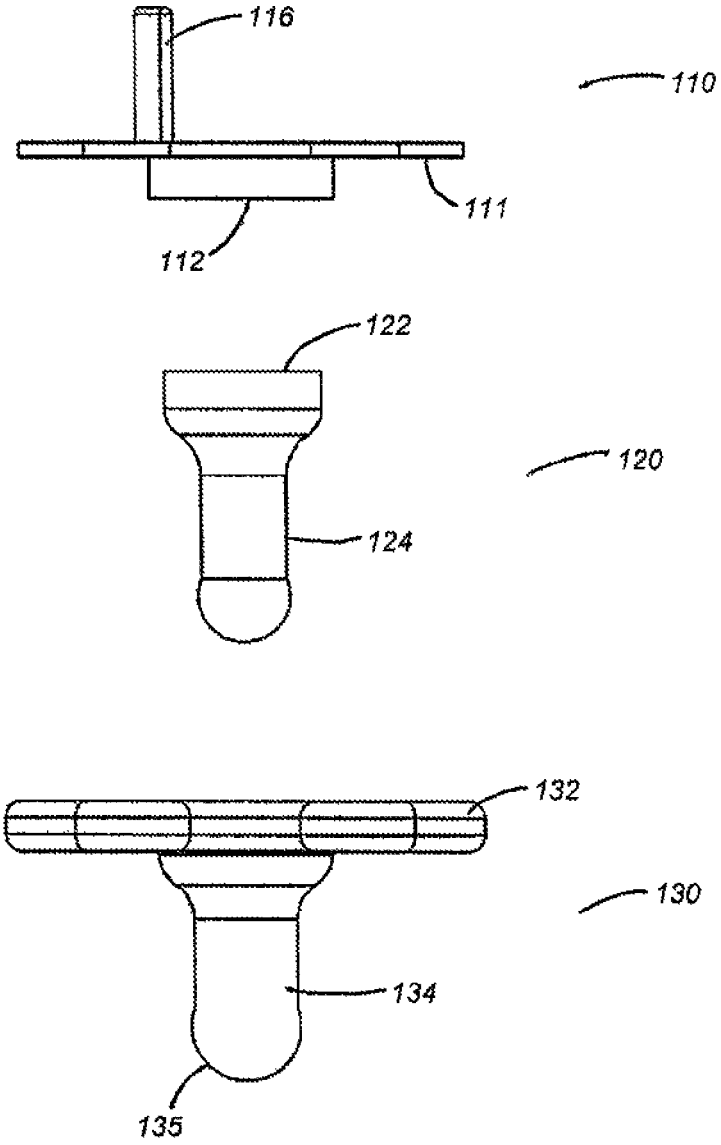

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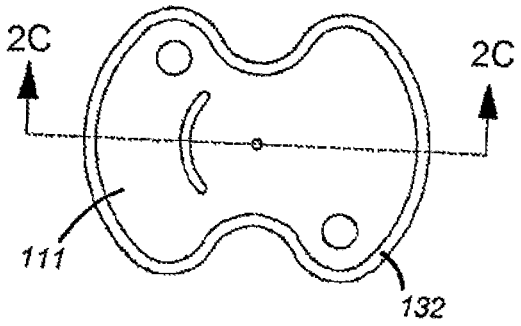

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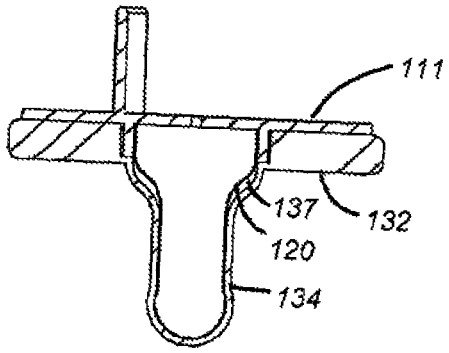

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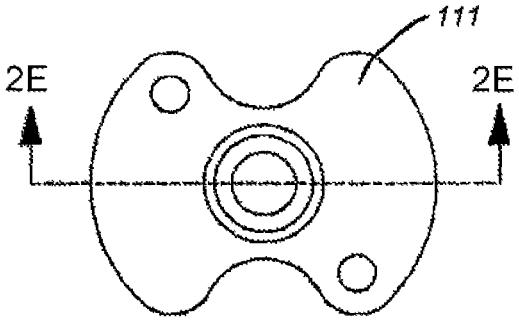

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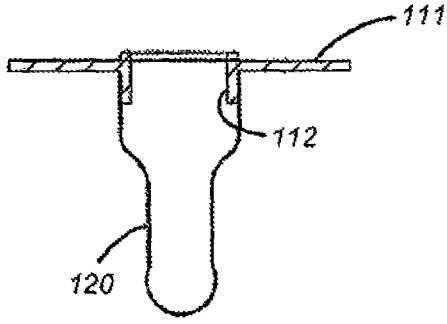
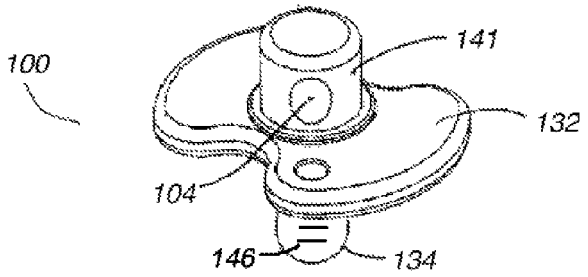
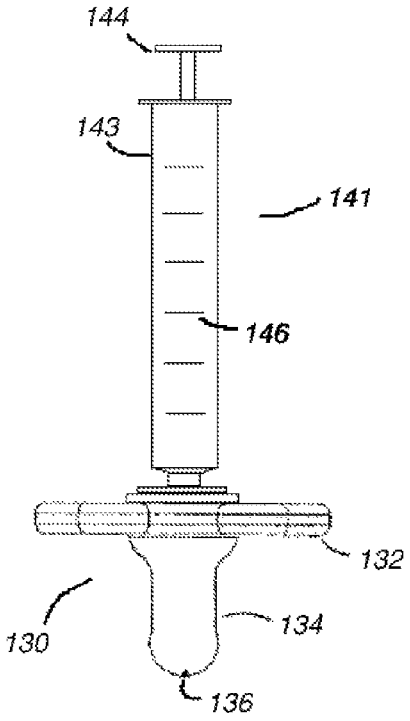


Figure 2E

Figure 3A





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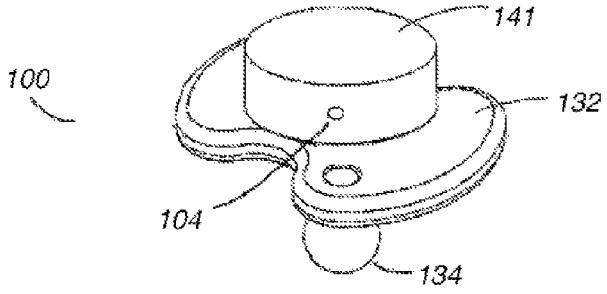

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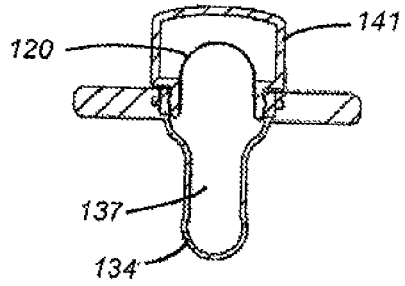

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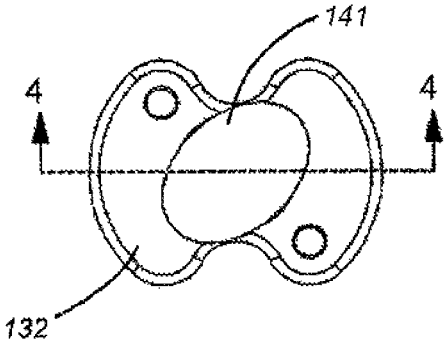

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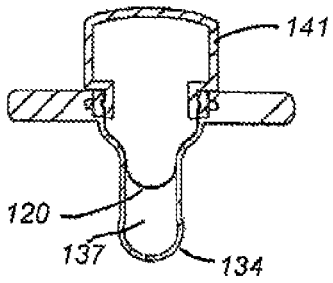

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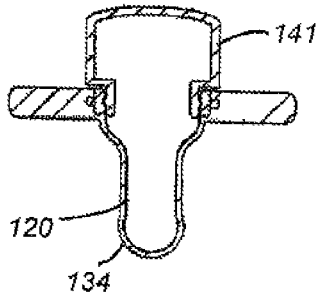

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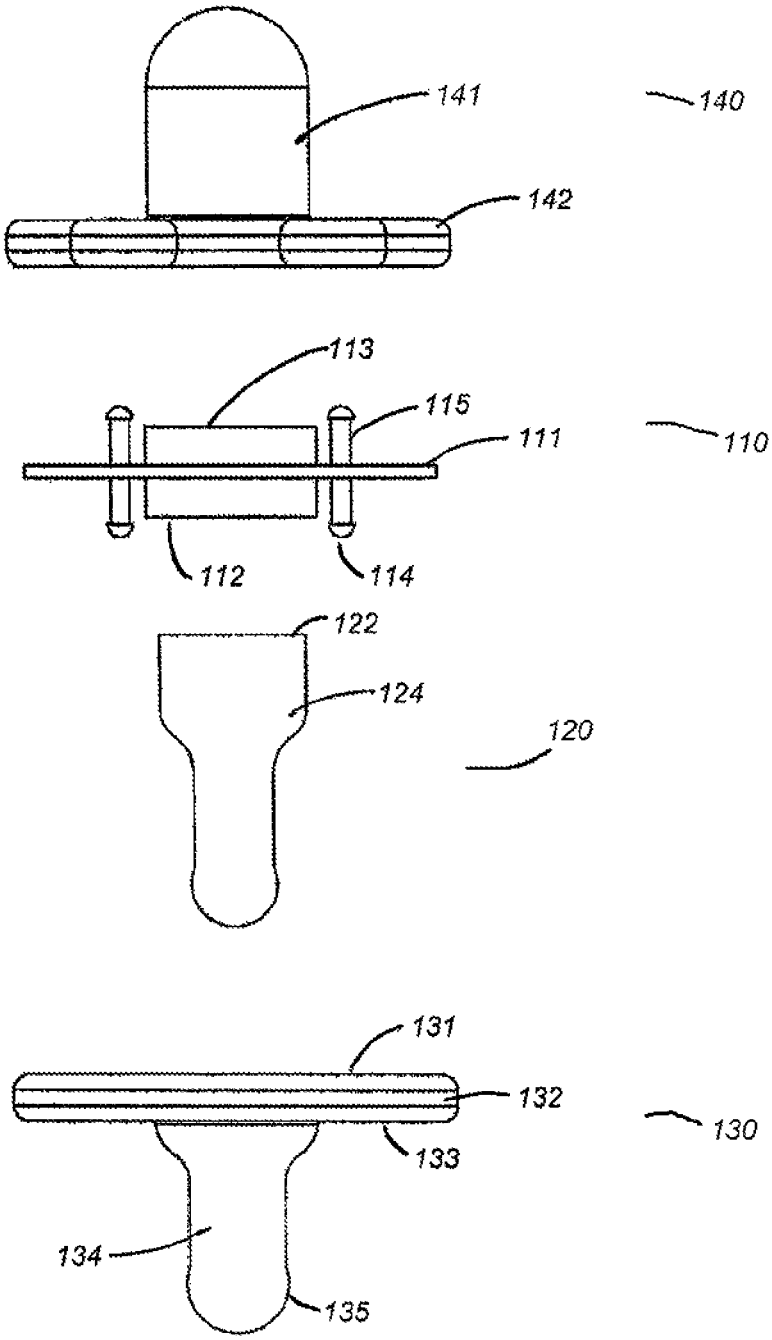
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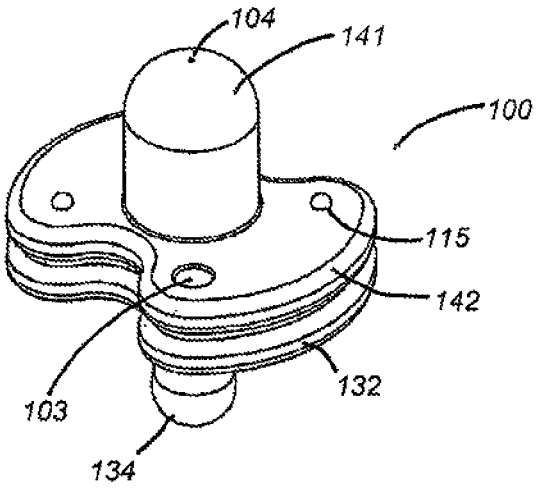
Figure 5A

Figure 5B



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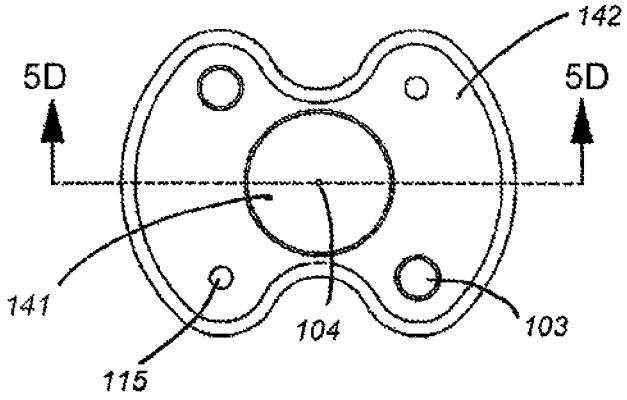

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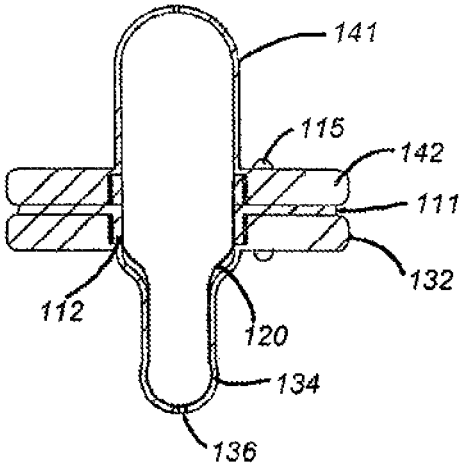

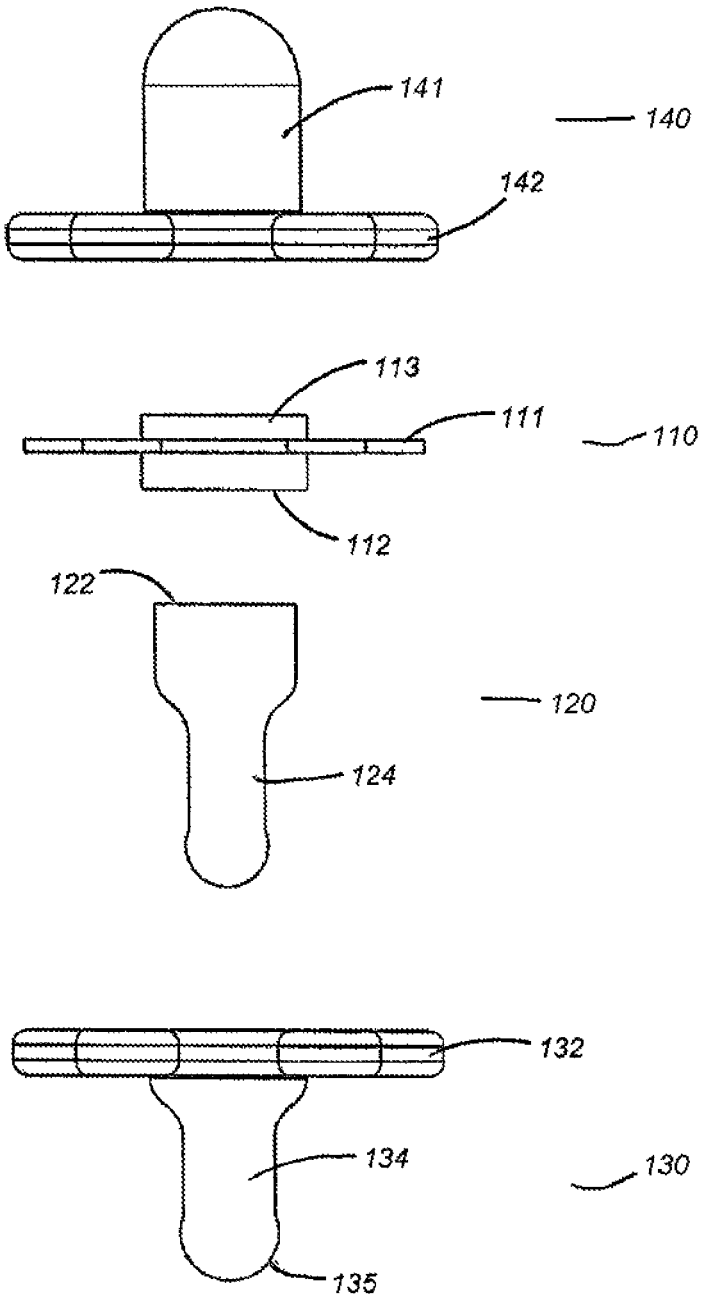

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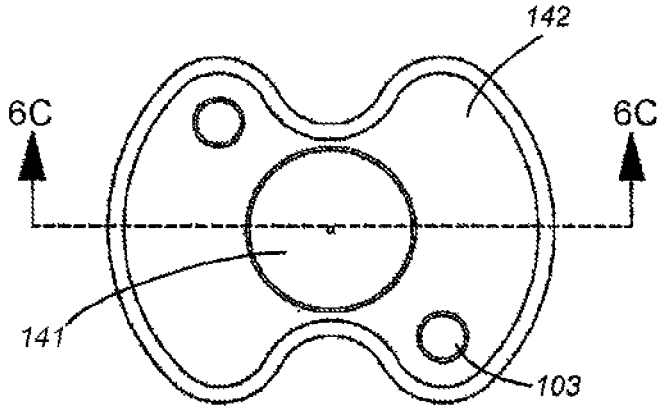

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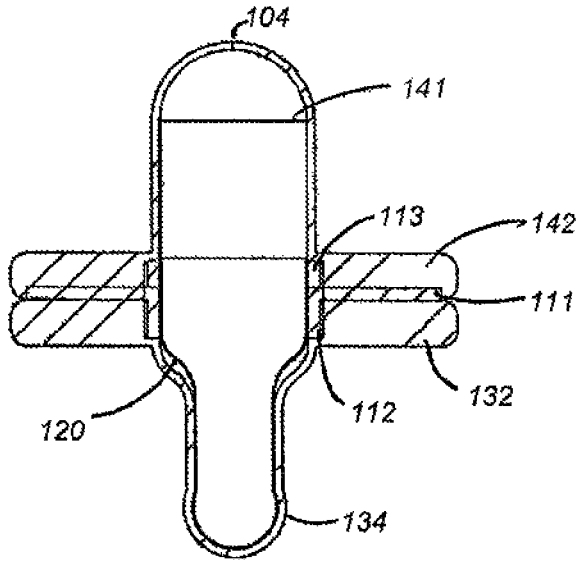

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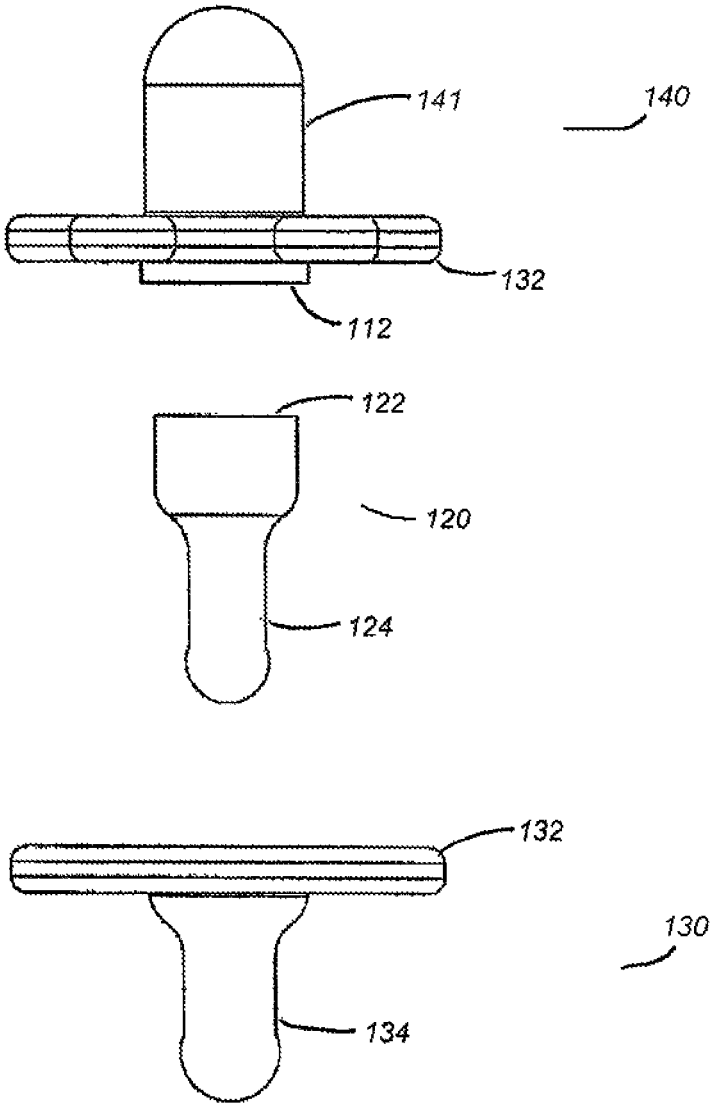

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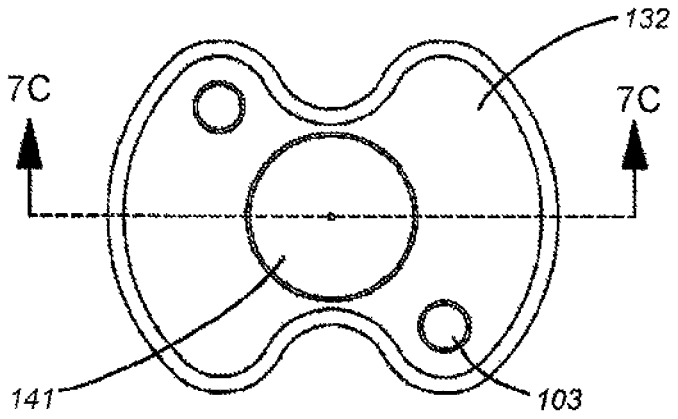

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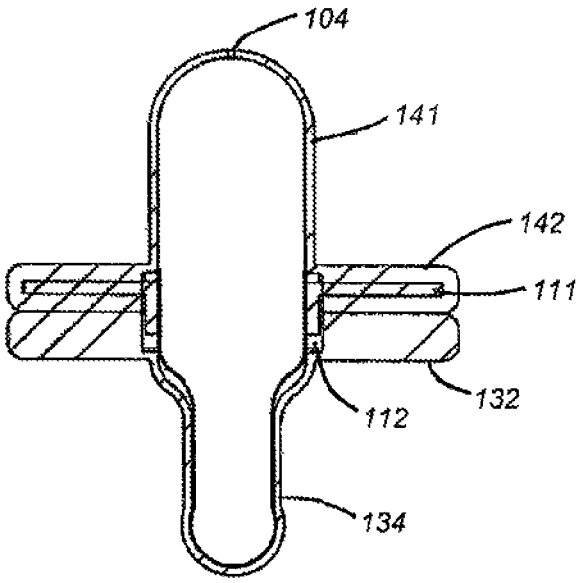

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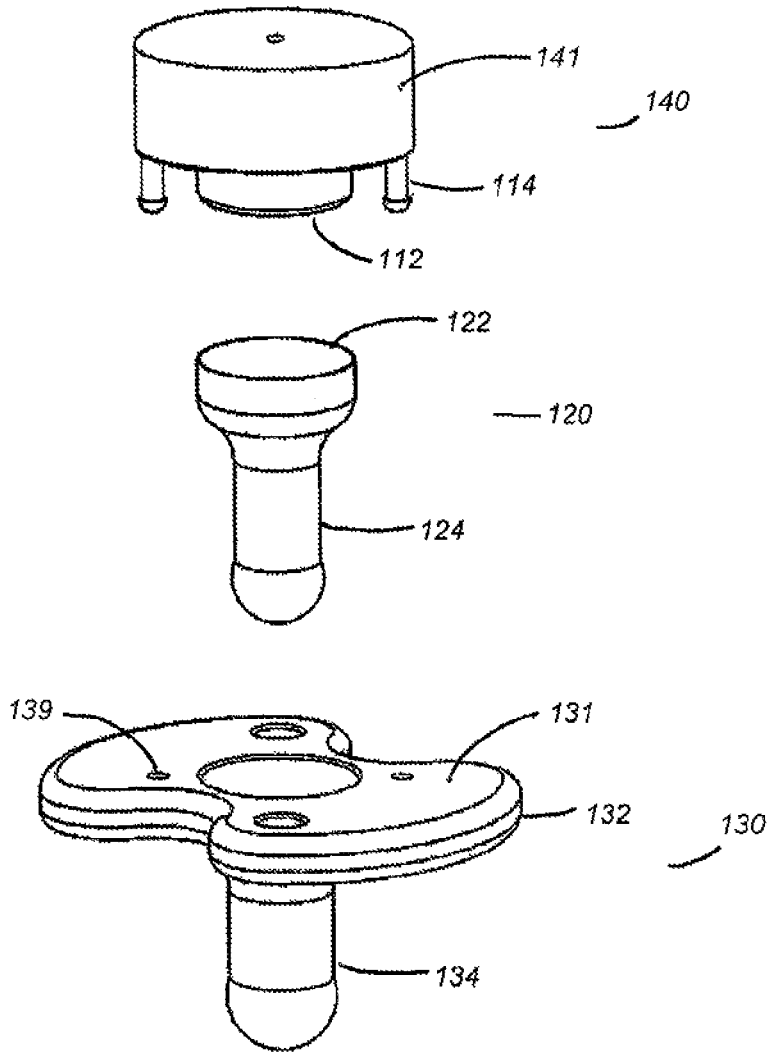

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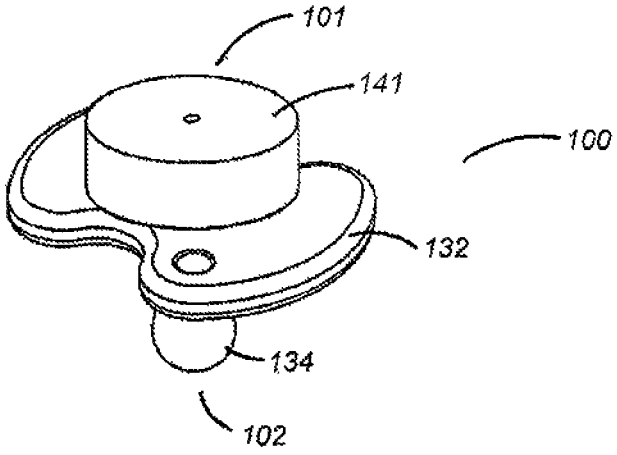

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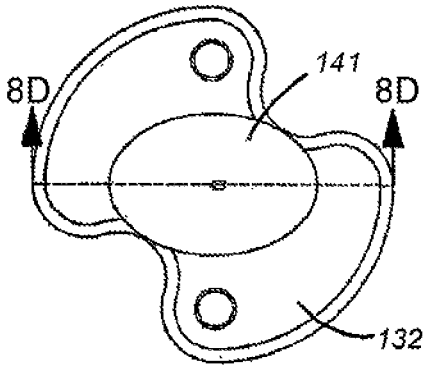

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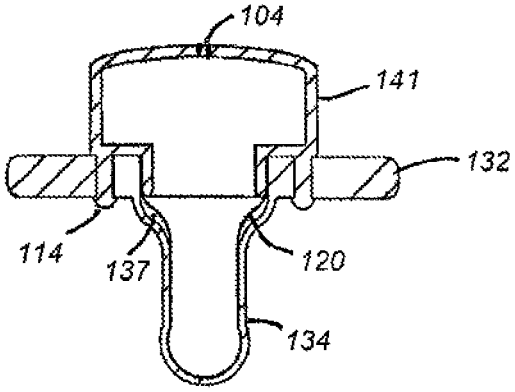

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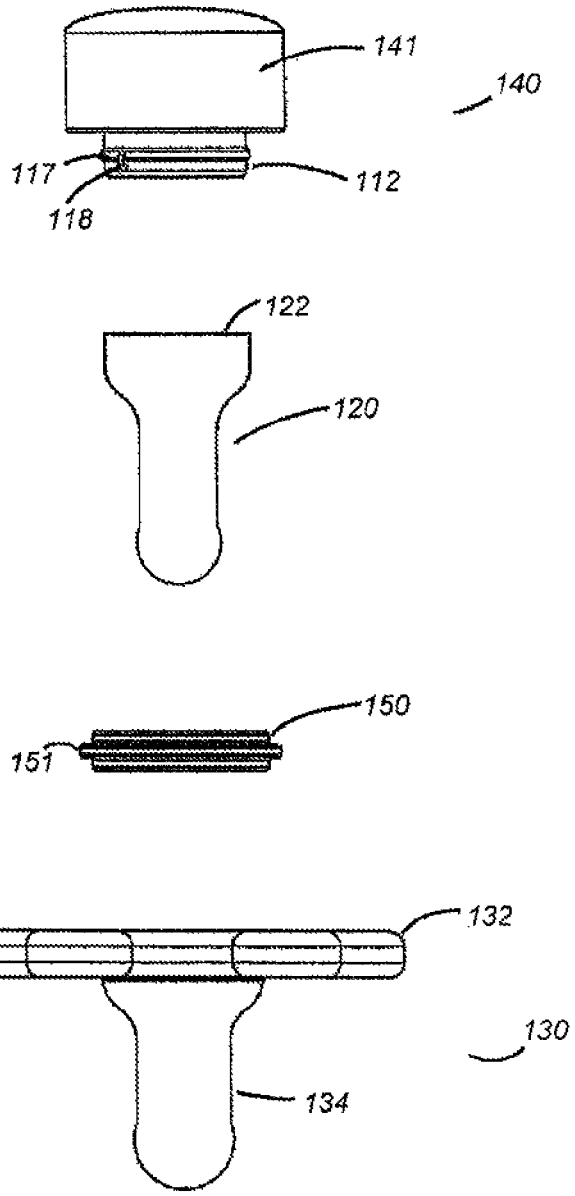

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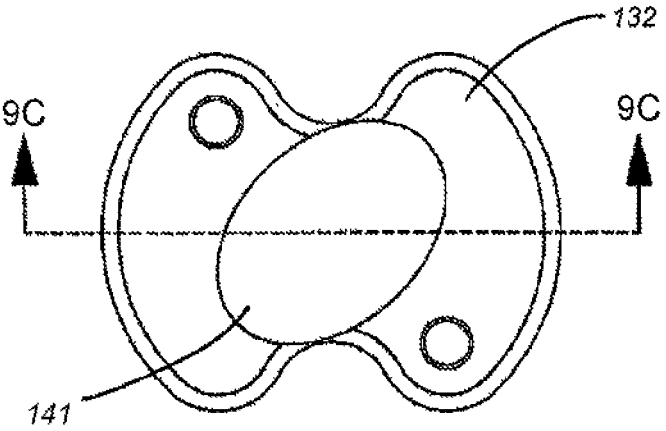

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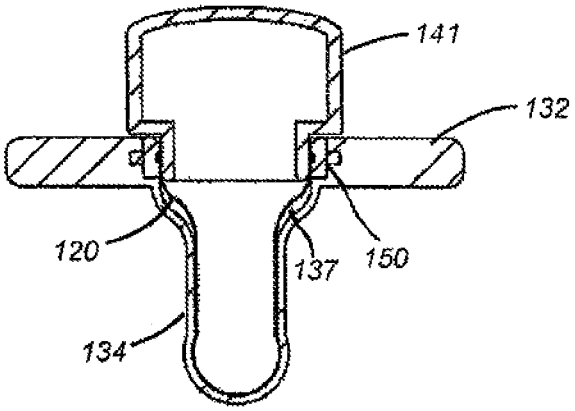

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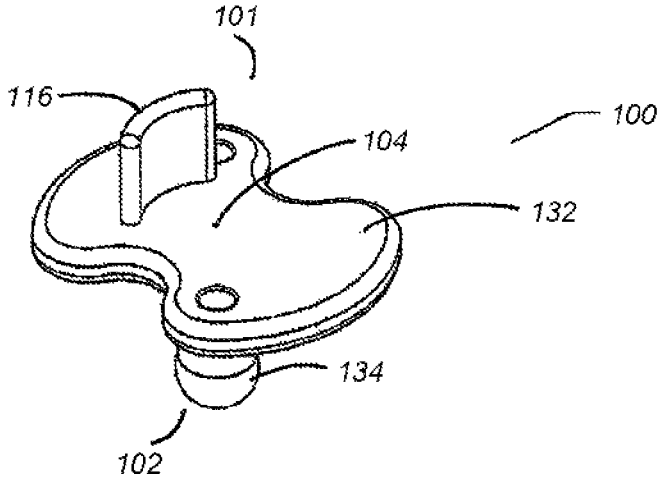

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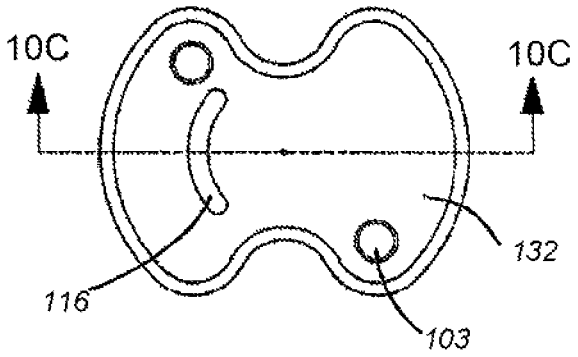

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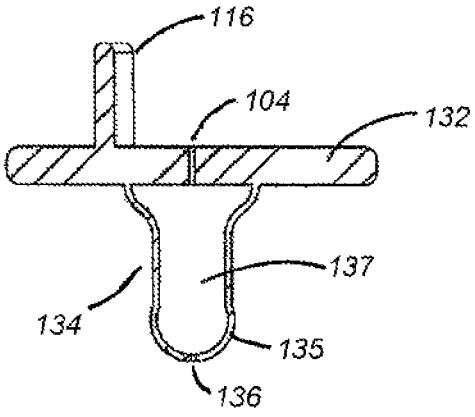

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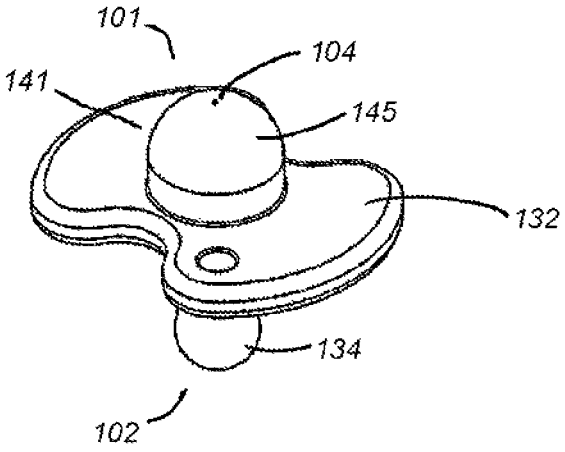


Figure 11A

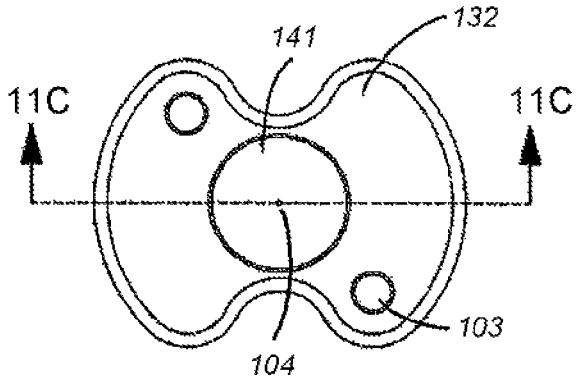
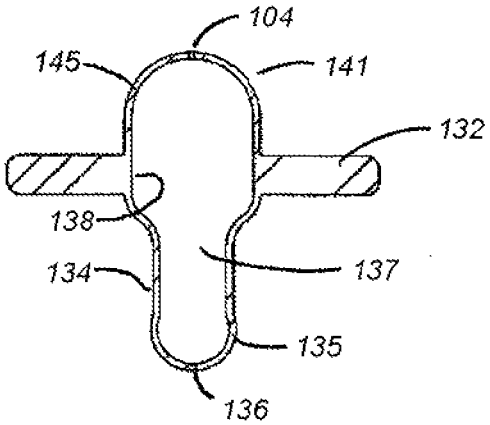


Figure 11B



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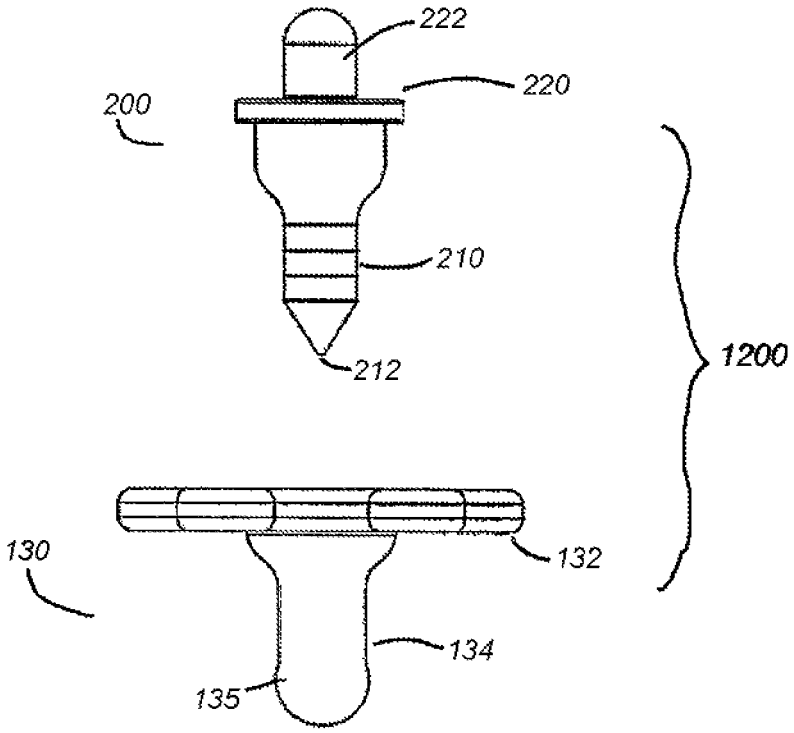


Figure 12A

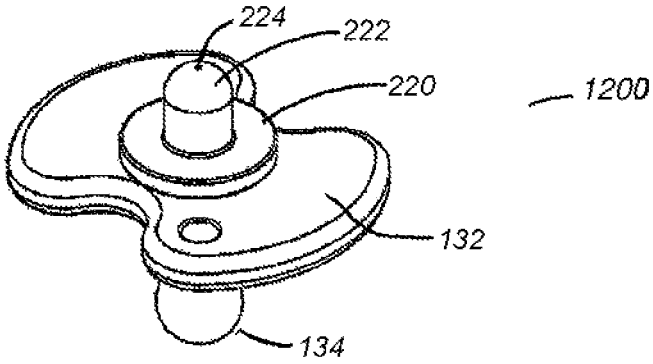


Figure 12B

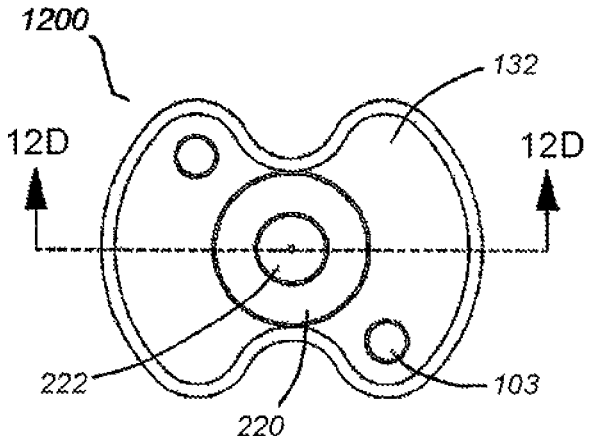


Figure 12C

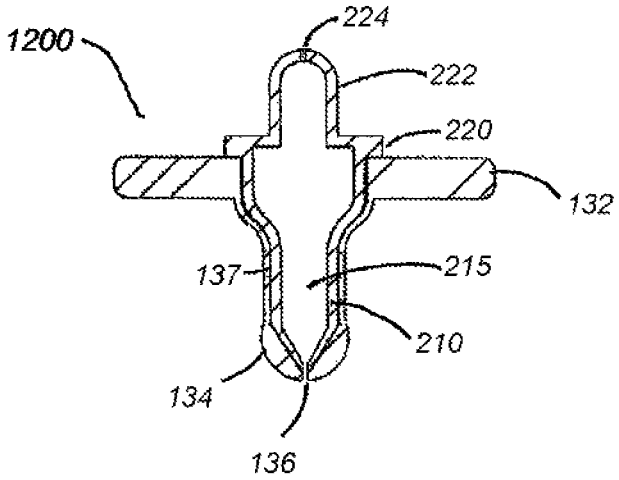


Figure 12D

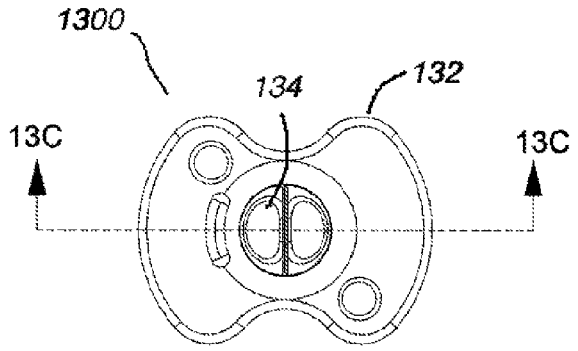


Figure 13B

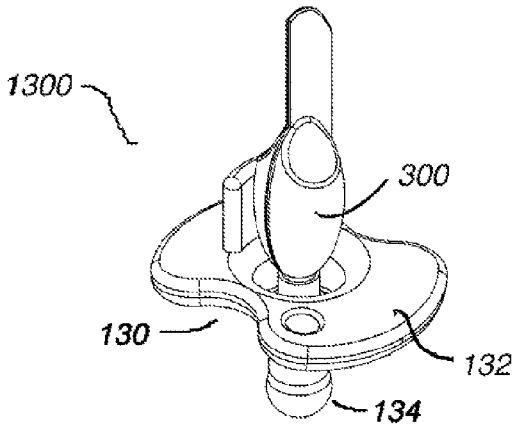


Figure 13A

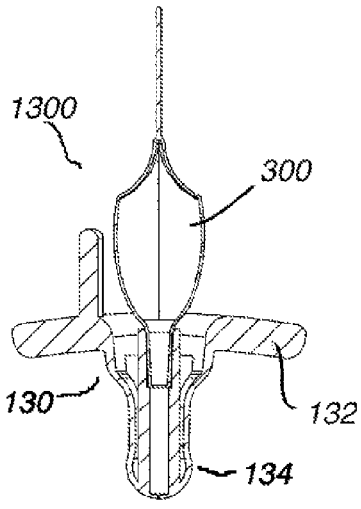


Figure 13C

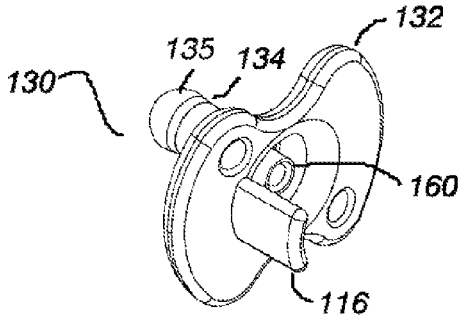


Figure 14A

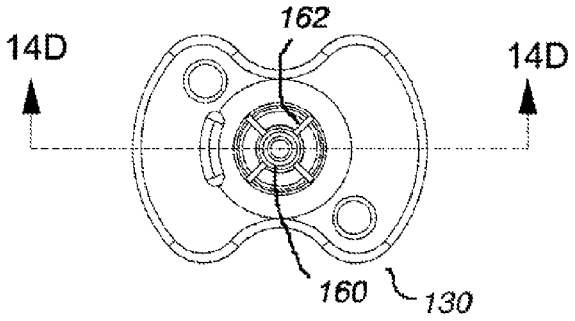


Figure 14C

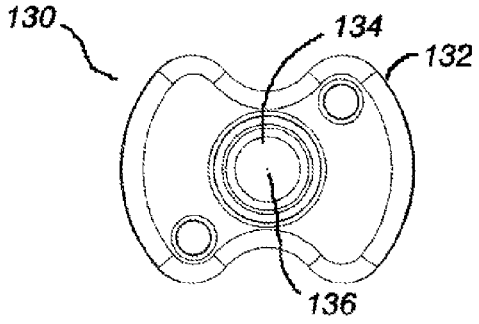


Figure 14B

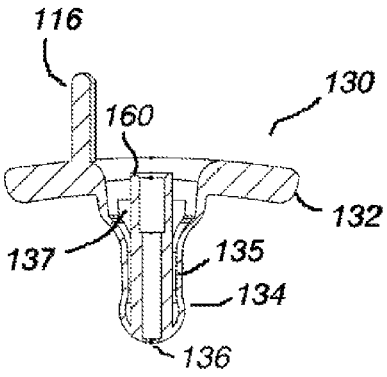


Figure 14D

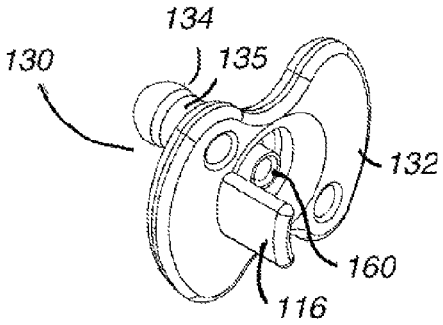


Figure 15A

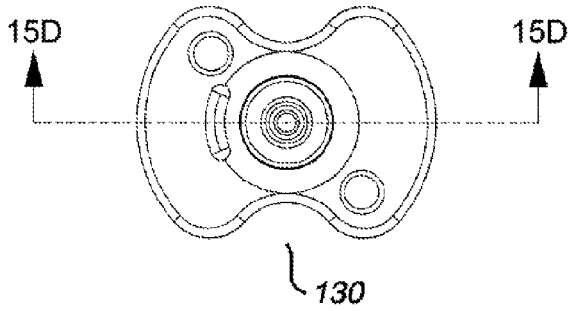


Figure 15C

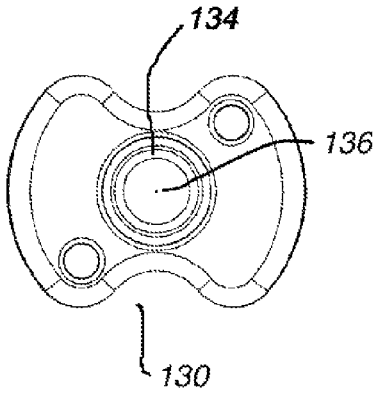


Figure 15B

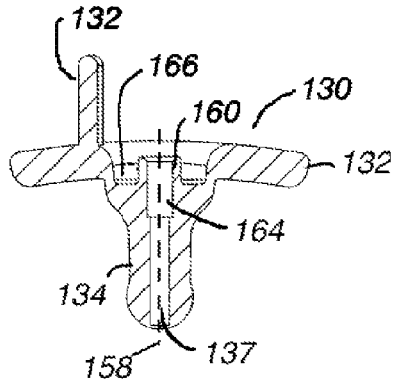


Figure 15D

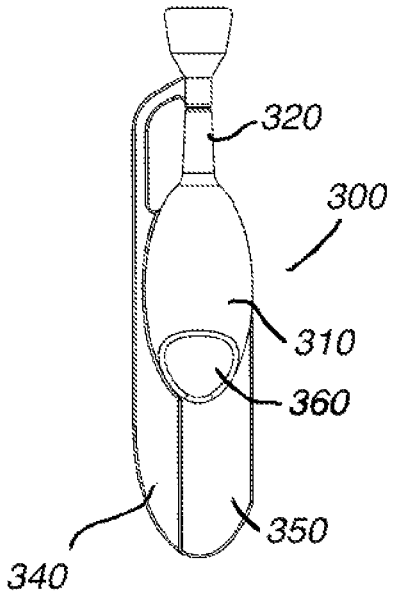


Figure 16A

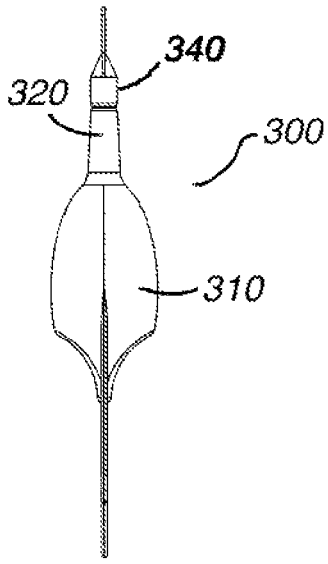


Figure 16B

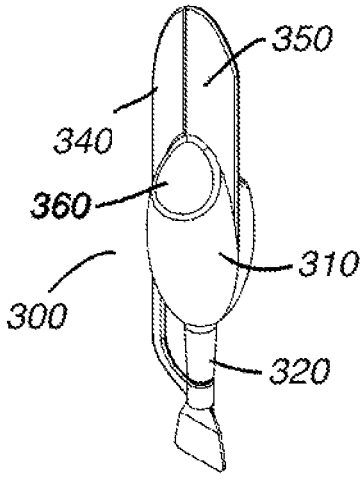


Figure 16C

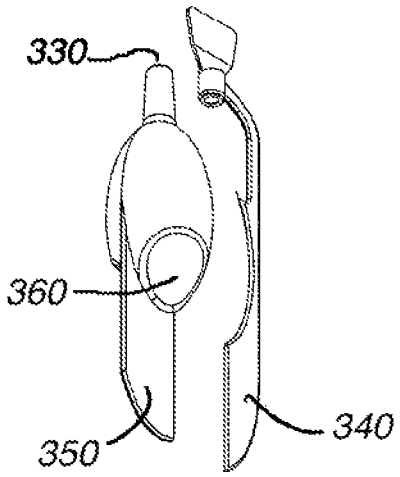


Figure 16D

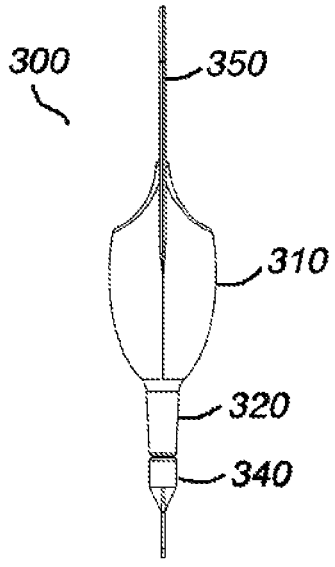


Figure 16E

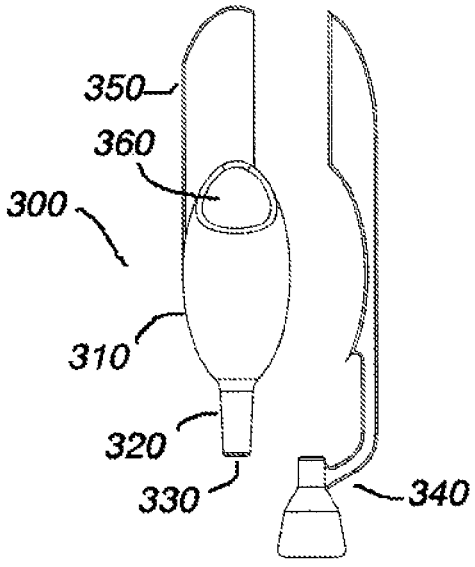


Figure 16F

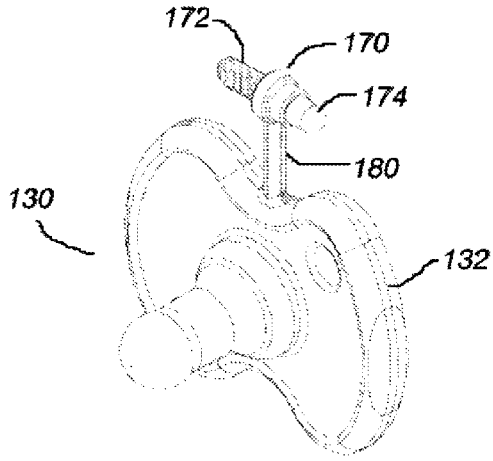


Figure 17A

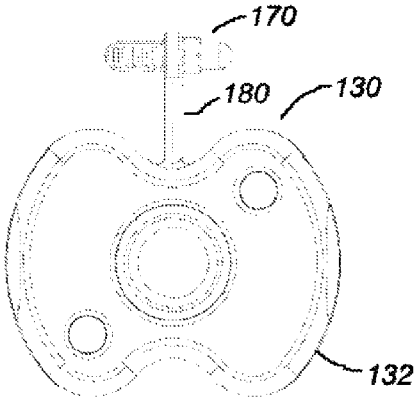
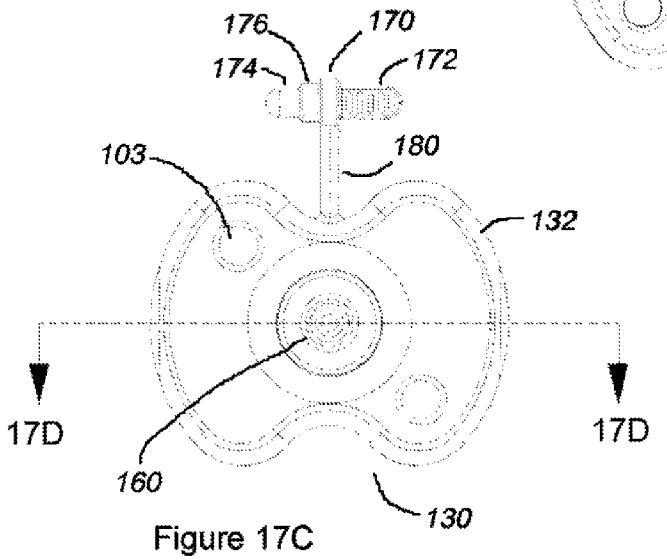


Figure 17B



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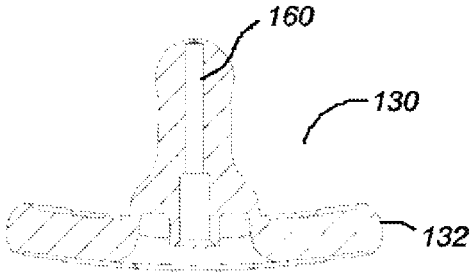


Figure 17D

Figure 17E

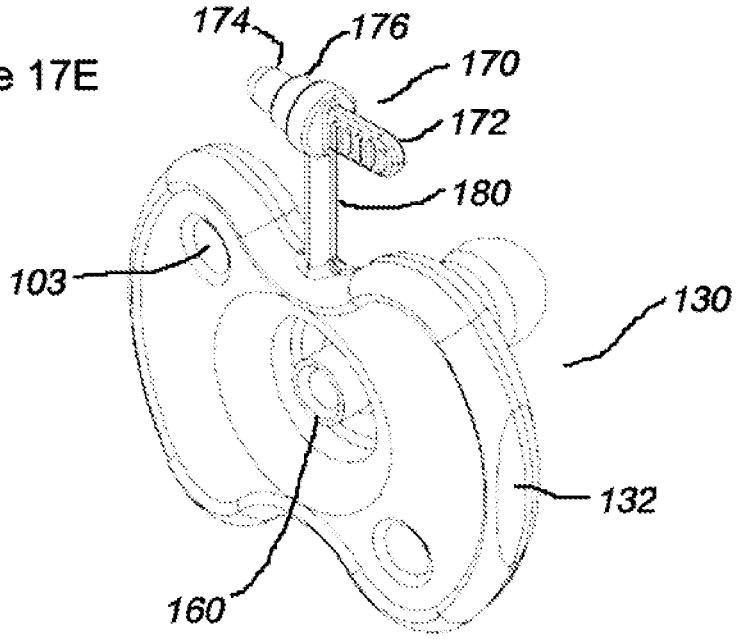
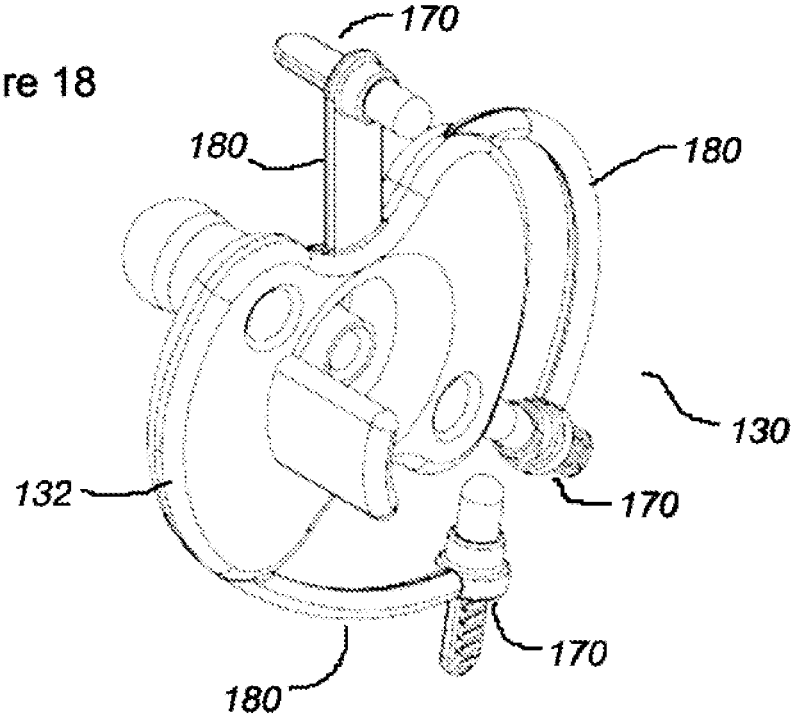


Figure 18



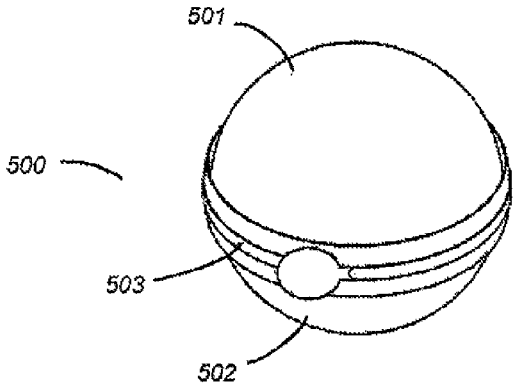


Figure 19A

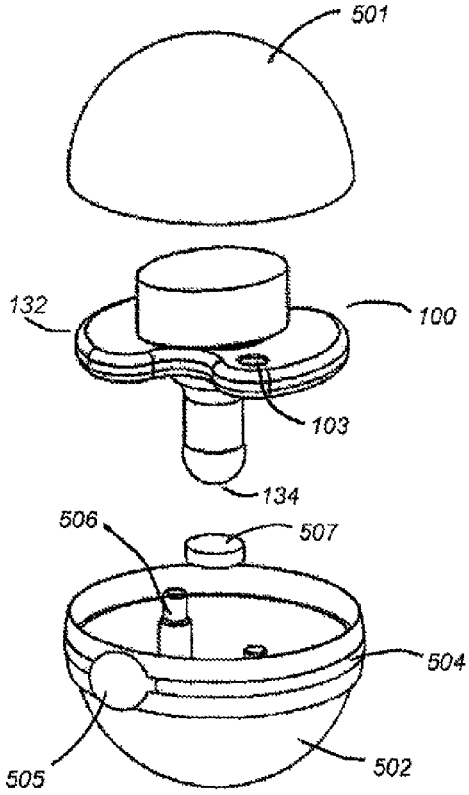


Figure 19B

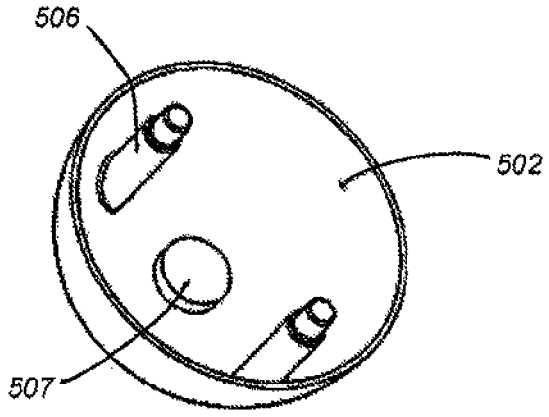


Figure 19C

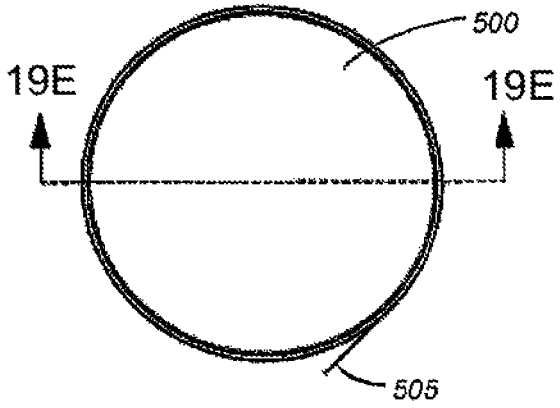


Figure 19D

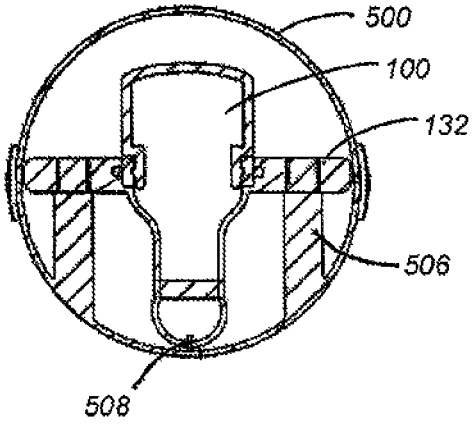


Figure 19E

Figure 20A

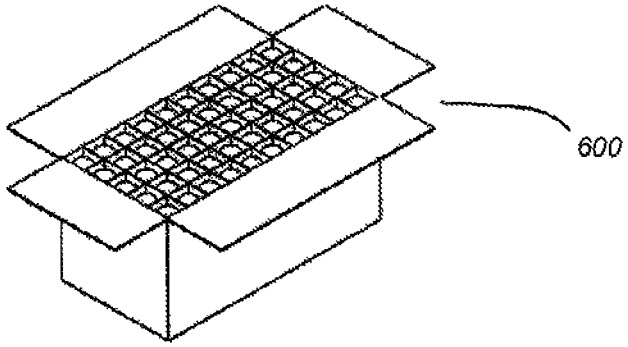


Figure 20B

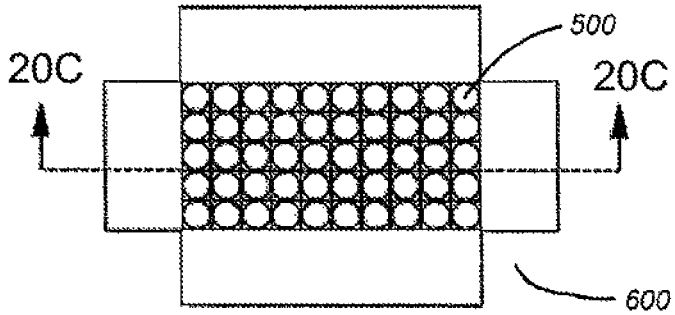
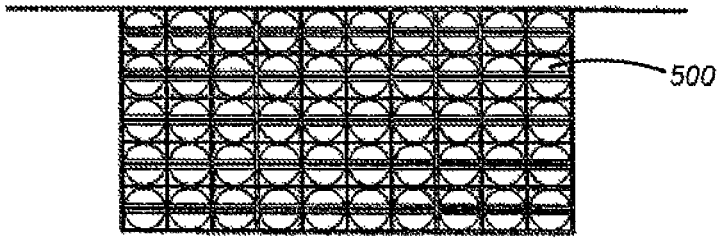


Figure 20C



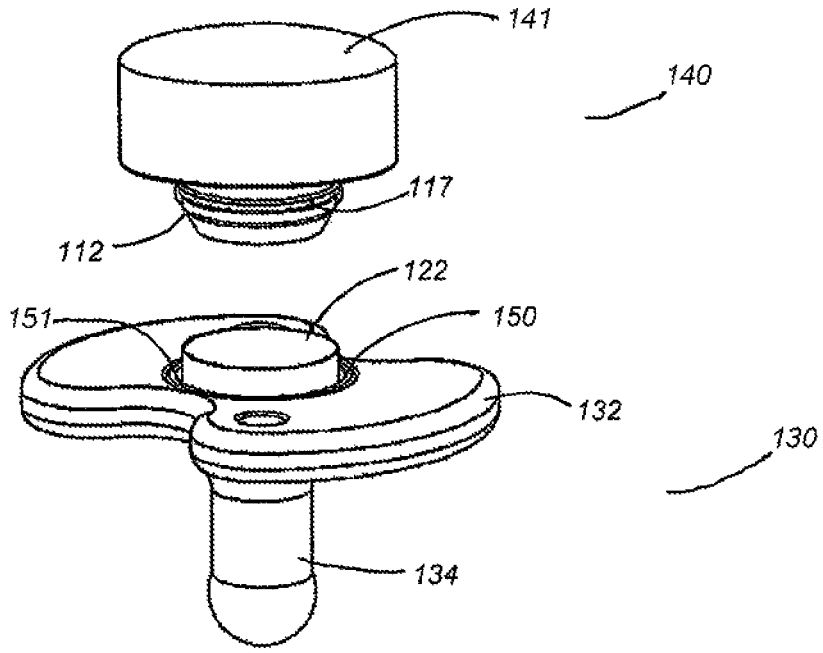


Figure 21

Figure 22

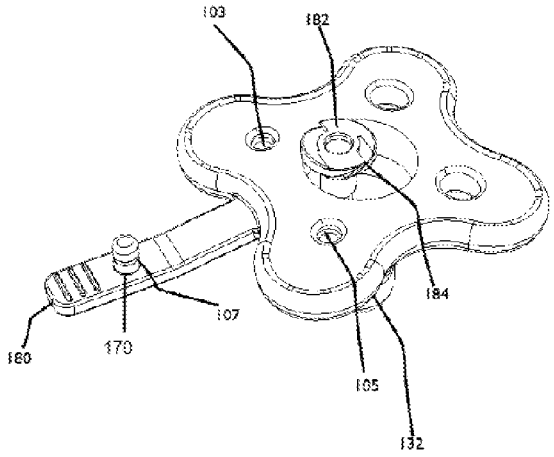


Figure 23A

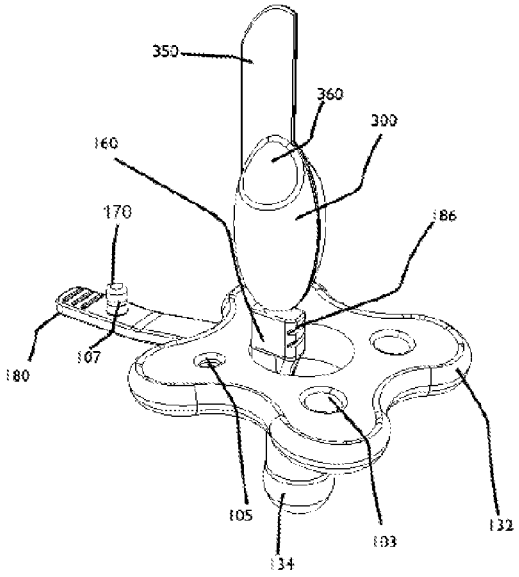
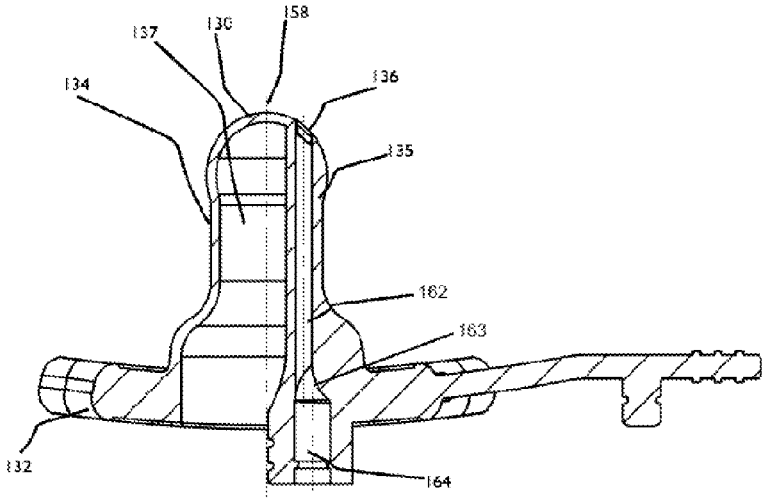


Figure 23B



APPARATUS AND METHODS FOR ORAL ADMINISTRATION OF FLUIDS AND MEDICAL INSTRUMENTATION

INCORPORATION BY REFERENCE TO ANY PRIORITY APPLICATIONS

This application is a continuation of U.S. application Ser. No. 14/062,736, filed Oct. 24, 2013, which is a continuation-in-part application of International Application No. PCT/US2013/037492 filed Apr. 19, 2013, which claims priority to U.S. Provisional Application 61/636,401 filed Apr. 20, 2012, U.S. Provisional Application 61/659,360 filed Jun. 13, 2012, U.S. Provisional Application 61/709,053 filed Oct. 2, 2012, and U.S. Provisional Application 61/802,141 filed Mar. 15, 2013. Each of the above-identified applications is hereby incorporated by reference in its entirety.

BACKGROUND

1. Field of the Invention

Embodiments disclosed herein relate to apparatuses, systems, and methods for administering fluids and medical devices. More particularly, the present disclosure describes a pacifier apparatus and related systems and methods for the oral delivery of fluids and medical instrumentation to promote health and well-being.

2. Description of the Related Art

Often when a neonate, infant, child, or any infirmed or injured individual is a patient in a hospital, the individual will receive multiple fluids and medications. The individual may also be attached to one or more medical devices and undergo one or more medical procedures during the hospital stay. The entire experience can be stressful and overwhelming. Patients benefit from being soothed and comforted while in the hospital.

Many parents and caregivers use pacifiers to relax and soothe their young children and to help them sleep. The most popular pacifier designs are rather simple devices formed of a nipple and a mouth guard. Many young children find comfort in a variety of settings by suckling on such pacifier nipples. Currently, a pacifier in the mouth of a patient must be removed before medications, fluids, or medical instrumentation can be administered orally.

SUMMARY

Circumcision, venipuncture, and diagnostic examinations are just a few of the painful and traumatic procedures to which newborns and infants are subjected. Several studies have shown that the neurons that convey painful stimuli are well developed in the newborn brain, and systemic stress from a painful stimulus may negatively affect major body systems. Accordingly, in recent years, the medical industry has begun to seek methods and apparatuses for reducing the pain experienced by infants during painful procedures. Studies have shown sucrose administration to be a safe and effective means of reducing procedural pain in the newborn. Other clinical research suggests that non-nutritive sucking in conjunction with sucrose intake provides a synergistic analgesic effect. Accordingly, medical centers are increasingly developing protocols for orally administering a sucrose serum to infants prior to performing painful medical procedures. In many hospitals, these protocols involve dipping a pacifier or a gloved practioner's finger into a sucrose solution and inserting it into an infant's mouth. Recently, more advanced pacifiers have been developed for dispensing sucrose, such as those discussed by Crowe et al. U.S. Pat. No. 5,772,685 and Stewart U.S. Pat. No. 8,118,773. However, there are many shortcomings associated with currently available designs.

Many existing pacifiers require that the fluid be injected into the device at the site where the procedure takes place. These designs lack an understanding of one of the most valuable and scarce resources in a healthcare facility—time. Previous devices and methods also include complex devices with multiple moving pieces and other advanced features. Such devices tend not to be user friendly, disposable, or well suited for one-time procedural use. Moreover, most current devices are not suitable for neonates who have not yet developed the ability to extract a fluid through sucking, due to prematurity of intraoral musculature, ankyloglossia, or the like.

Available devices also neglect the lifecycle of pre-procedural, intra-procedural and post-procedural pain. Studies have shown that the peak effects of sucrose are delayed for two minutes upon administration and the analgesic response to sucrose lasts nearly four minutes. Also, post-procedural symptoms such as tachycardia, increased breathing, and pain can be mitigated through additional ingestion of sucrose after a procedure. Recent studies suggest that for optimal analgesic effect to occur, a controlled dose of an analgesic over a given period of time is superior to larger, uncontrolled quantities of analgesic given in a shorter period of time. Accordingly, a need exists for a device which can adjust for procedural time by expressing a precise and targeted amount of fluid during a short duration procedure, while also extending the expression time to provide post-procedural analgesic effects during a longer procedure. However, such devices are lacking in the market. There is still a gaping need for a fluid dispensing/fluid administration apparatus that requires minimal effort to prepare on the part of a health care practitioner and can also provide an analgesic effect (or other comfort/relief) throughout the length of a procedure and post-procedure.

The market also lacks a device which can express, store, and orally administer colostrum using, in part, a fluid administration device specifically tailored for premature infants and other neonates. Colostrum is known to contain antibodies, growth factors, and anti-inflammatory agents important for the development of a child's immune system. It is important for all infants, even those who have not yet developed the ability to extract a fluid through sucking, to receive their mother's colostrum soon after birth.

Currently available fluid administration devices also fail to sufficiently address the problems that exist in the outpatient, home use, and commercial markets where issues related to currently available devices have recently led to recalls of major fever and pain relieving drugs. A need exists for a fluid administration apparatus configured to expel a precise and targeted dosage of fluid to an infant or other individual. It would be particularly advantageous to have a fluid administration apparatus capable of administering a targeted dosage of a medicament to an infant or patient in a soothing and familiar manner with a controlled flow rate. A need also exists for a fluid administration apparatus that allows infants to ingest a premeasured amount of medication at their own natural rate of suckling.

Additionally, the market, especially the hospital market, currently lacks a device that can be used as a soother, and when necessary, can be used as a medical delivery platform as well. It would be advantageous to have a soothing pacifier that can receive multiple medical accessories and devices,

such as, for example, for the oral delivery of catheters, imaging scopes, intubation tubes, and/or transitional feeding attachments.

As a result of these gaps in the market, a need exists for an improved device capable of addressing one or more of the above-mentioned needs.

Disclosed herein are various embodiments of a fluid administration apparatus or pacifier, and related systems and methods, which may fill one or more of the aforementioned needs of the inpatient and outpatient markets. It is conceived that embodiments of the present technology may be used to administer any desired substance, including for example, analgesics, probiotic cultures, vitamins, nutritive solutions, colostrum, breast milk, antibiotics, anti-gas solutions, over-the-counter medicaments, other liquid medicaments, and other fluids. Some embodiments may additionally or alternatively be used as a medical platform used in the oral delivery of medical instrumentation.

While various examples disclosed herein are directed to neonates, infants, and/or children, this is merely done to simplify the description. It should be understood that the present embodiments are in no way limited to use within those exemplified populations. All apparatuses, systems, methods, and kits disclosed herein may also be used with geriatric populations and children and/or adults who struggle with oral-muscular activities, such as swallowing solid foods, due to disability or incapacitation. Additionally, embodiments disclosed herein may be utilized in a veterinary setting.

Some embodiments of the disclosed apparatus and system: are disposable, limit a receiving individual's ingestion of air, and/or provide a mechanism for expelling fluid into the mouth of a receiving individual when the individual is unwilling or unable to suck. Some embodiments of the devices, systems, and kits disclosed herein are configured to dispense fluid at any angle regardless of the position of the fluid-receiving individual. Additionally or alternatively, some embodiments provide a measurement of the amount of fluid expelled from the fluid-administrating apparatus. In some embodiments disclosed herein, the apparatus provides a controlled flow rate upon actuation (e.g., squeezing by a caregiver and/or sucking by a fluid-receiving individual) to ensure adequate fluid administration, prevent unnatural flow, and eliminate gag and choking responses.

It should be understood that the apparatuses, systems, and methods of the present technology have several features, no single one of which is solely responsible for the desirable attributes described herein. Without limiting the scope, as expressed by the claims that follow, the more prominent features will be briefly disclosed here. After considering this discussion, one will understand how the features of the various embodiments provide several advantages over traditional pacifiers and current fluid administration devices.

Several embodiments of the present technology are directed to a pacifier apparatus configured for administering fluid. In one disclosed embodiment, the pacifier apparatus includes, at least, a nipple base and a nipple. The nipple base of some embodiments includes, for example, a proximal face, a distal face, and a passage wall defining a passage extending through the base, and the nipple extends proximally from the proximal face. The nipple of some embodiments includes, for example, a nipple wall having a distal end coupled to the nipple base and a nipple aperture at a proximal tip. The nipple wall defines a cavity configured to hold a fluid, and the nipple of various embodiments is configured to expel the fluid through the nipple aperture in response to the nipple being sucked.

The pacifier apparatus of some embodiments also includes a balloon. The balloon of some embodiments has, for example, a body and a distal mouth coupled to the nipple base, and the balloon of some embodiments is configured to transition from at least a substantially undeployed state to a substantially deployed state in response to the nipple being sucked. In the deployed state of various embodiments, the balloon body is configured to extend into the cavity and substantially block the passage of air through the nipple aperture, signal complete medicine intake, and eliminate further fluid flow. In some embodiments of the apparatus, the balloon, in the deployed state, has a size and shape relatively comparable to the size and shape of the nipple. In such embodiments, the balloon is configured to substantially line an inner perimeter of the nipple wall when fully deployed. Deployment of the balloon may facilitate expulsion of fluid from the nipple cavity through the nipple aperture.

Some embodiments of the apparatus further include a rigid member positioned at least partially within the passage of the nipple base. The rigid member of some embodiments is configured to provide a mechanism for securing the distal mouth of the balloon relative to the nipple base, and in some embodiments, the distal mouth of the balloon is affixed around or within the rigid member.

The pacifier apparatus of some embodiments further includes a pump. In various embodiments, the pump may be configured as an alternate mechanism for expelling solution from the device and/or for transitioning the balloon toward the deployed state and for thereby expelling fluid from the nipple aperture. In some embodiments, the pump is shaped, for example, as a syringe having a syringe body and a plunger. In some embodiments, the rigid member extends from the pump and is configured for positioning within the passage of the nipple base. The rigid member may be integrally coupled to the pump, for example. In some such embodiments, the apparatus further includes, for example, a locking ring positioned around the distal mouth of the balloon such that the distal mouth and the locking ring are positioned between the rigid member and the passage wall, securely coupling the distal mouth of the balloon, the locking ring, the rigid member, and the nipple base together. In some of these embodiments, at least a portion of the locking ring is affixed within the nipple base. The rigid member of some embodiments includes a coupling element, for example, a ridge, a perforation, an indentation, or threading for coupling the rigid member to the locking ring. In one embodiment, the balloon mouth is positioned around a proximal portion of the rigid member, and a distal portion of the rigid member, which includes the coupling element, is configured to couple directly to the locking ring. In another embodiment, the rigid member is configured to couple indirectly to the locking ring, with the distal mouth of the balloon positioned between the coupling element of the rigid member and the locking ring.

In some embodiments, the apparatus further includes a pump base fixedly connected to a proximal end of the pump. In some such embodiments, the rigid member extends proximally from the pump base and is configured for positioning within the passage of the nipple base. In such embodiments, at least a proximal portion of the rigid member is configured to securely engage the distal mouth of the balloon and be positioned within the passage of the nipple base, and a distal portion of the rigid member is configured to securely engage the pump base. In some such embodiments, the rigid member may be integrally connected with the pump base.

In other embodiments, the rigid member extends proximally from a rigid plate and is positioned within the passage of the nipple base. In some embodiments, the rigid plate includes a distally extending handle. In the alternative or in addition, the rigid plate of some embodiments includes a second rigid member extending distally from the rigid plate. In some such embodiments, the second rigid member is configured to engage with a pump. In others, the second rigid member is configured to engage with a pump base. In some embodiments, a pump in the form of a syringe extends from, and removably couples to, the rigid plate. In various embodiments, the apparatus additionally or alternatively includes one or more anchors extending from the rigid plate and/or from the pump or pump base, which are configured to extend through a plurality of holes in the nipple base to fixedly secure the rigid plate and/or the pump to the nipple base.

In another disclosed embodiment, an apparatus for administering fluid includes a pacifier apparatus having an integral, unitary body. In some embodiments, the unitary pacifier includes, for example, a nipple base having a distal face and a proximal face, a nipple extending proximally outward from the proximal face, and optionally, a handle extending distally outward from the distal face. The nipple of some embodiments includes, for example, a nipple wall configured for sucking, and the nipple wall and a portion of the proximal face define a substantially closed cavity configured to hold a fluid. The pacifier of several embodiments also includes, for example, a nipple aperture at a proximal tip of the nipple and a distal opening to the cavity in the nipple base.

In other embodiments, the unitary pacifier apparatus includes, for example, a nipple base having a distal face, a proximal face, and a passage wall defining a passage extending through the nipple base, a nipple extending proximally outward from the proximal face, and a depressible pump extending distally outward from the distal face. The nipple of various embodiments includes, for example, a nipple wall configured for sucking, and the depressible pump includes a compressible wall configured for squeezing or applying force. The nipple wall and compressible wall each connect with the passage wall to define a cavity configured to hold a fluid. The pacifier of some embodiments further includes, for example, a nipple aperture at a proximal tip of the nipple and a distal opening to the cavity through the depressible pump. In some embodiments, the distal opening to the cavity includes, for example, one or more of a valve, a hole, a slit, and a frangible seal. In some of the above-mentioned embodiments, the pacifier apparatus having a unitary body is formed of a material that includes one or more of silicone, plastic, rubber, and other polymers.

In another disclosed embodiment, a pacifier apparatus configured for administering fluid includes, for example: a nipple base having a proximal face, a distal face, and a passage extending through the nipple base; and a nipple extending proximally from the proximal face and having a nipple wall, which defines a cavity, is configured for sucking, and has a nipple aperture at or near a proximal tip. In some embodiments, the nipple aperture is disposed along a bulbous proximal end of the nipple offset from the proximal tip; in some such embodiments, the distal opening to the cavity is axially aligned with the off-center nipple aperture. The apparatus of this embodiment can be configured, for example, to securely couple to a cartridge such that at least a portion of the cartridge is positioned within the passage and the cavity. In some embodiments, the apparatus includes a receiving tube disposed within the cavity and the passage, wherein the receiving tube is sized and configured to securely couple to a proximal portion of a cartridge. In some embodiments, the apparatus may include a plurality of receiving tubes disposed within the cavity and the passage. In some embodiments, these one or more receiving tubes run along a length of the nipple wall.

In another disclosed embodiment, a nipple apparatus, such as a pacifier, is configured for the oral administration of healthcare products. Healthcare products is a broad term encompassing any product, composition, or device used in the promotion of health or treatment of disease, including, for example, medicines, nutritional supplements, vitamins, nutraceuticals, breast milk, analgesics, fluids, colostrum, and any healthcare accessory, such as, for example, imaging scopes, intubation tubes, and enteral feeding syringes. In some embodiments, the nipple apparatus includes: a nipple base having a proximal face, a distal face, and a passage extending through the nipple base; a nipple extending proximally from the proximal face, the nipple defined by a contoured nipple wall having a nipple aperture disposed on a proximal end of the nipple wall; a receiving tube extending through the nipple and at least a portion of the passage, the receiving tube having a proximal portion which terminates at the nipple aperture; an attachment mechanism disposed in or on the receiving tube for attaching the receiving tube to a healthcare accessory; and an occlusion mechanism coupled to the receiving tube for selectively occluding the receiving tube. The occlusion mechanism may be any suitable structure which non-permanently occludes the flow of air through the receiving tube. Such a structure may limit the ingestion of air by a user. In some embodiments, the occlusion mechanism includes one or more valves, which selectively occlude the receiving tube by remaining closed and occluding the flow of air through the receiving tube until acted on by a force, such as, for example, the insertion of a cartridge into the receiving tube or the expulsion of fluid from the cartridge. In other embodiments, the occlusion mechanism includes one or more plugs. Such plugs are removably coupled to the receiving tube, and can be inserted into, or removed from, a distal end of the receiving tube to selectively control occlusion of air through the receiving tube. In other embodiments, the occlusion mechanism includes one or more healthcare accessories, which when coupled to, and disposed at least partially within, the receiving tube, occlude the flow of air through the receiving tube. In some embodiments, the attachment mechanism includes threading, snap fitting, slip fitting, friction fitting, or other coupling features to couple the receiving tube to a healthcare accessory, such as, for example, a cartridge.

The cartridge to which the apparatus may be configured to couple includes, for example, a reservoir configured to hold a fluid and a cartridge aperture at a proximal tip or end of the cartridge. In some embodiments, the cartridge also includes, for example, a pump, a repeatably deformable wall, or other actuator for causing the fluid to be expelled from the reservoir. When such a cartridge is properly coupled, the apparatus is configured to expel a fluid from the reservoir through the cartridge aperture and out of the apparatus through the nipple aperture at least in response to the pump being squeezed. Additionally or alternatively, in some embodiments, the cartridge is configured to expel a fluid from the reservoir through the cartridge aperture and out the apparatus through the nipple aperture at least in response to experiencing negative pressure from an infant's suck.

An embodiment of a system for dispensing fluid is also disclosed. In one embodiment, the system includes, for example, a cartridge containing a predetermined volume of

a predetermined fluid. The cartridge includes a reservoir configured to hold a fluid and a cartridge aperture at a proximal tip of the cartridge. The cartridge may also include a pump or other actuating features on a distal portion of the cartridge. As used herein throughout the specification and claims, the term "cartridge" is used to describe any ampoule, vial, syringe, or other container configured to hold and expel a quantity of liquid. In some embodiments, the cartridge is hermetically sealed. The seal may be wholly or partially removable. In some such embodiments, both the cartridge and the seal are sized so as not to pose a choking hazard to young children. In some embodiments, such a cartridge is manufactured using a blow fill seal, injection molding, or other process. In one embodiment, the reservoir may be in the form of a syringe body and the pump may be in the form of a plunger. The cartridge of various embodiments is configured to securely couple to the apparatus described in the previous paragraph or elsewhere herein. Such a cartridge may also be used independently to expel fluid into the mouth of an infant or other individual.

In some embodiments, the system is further configured for a single use; in some embodiments, the system includes at least one disposable cartridge and a reusable pacifier apparatus having the characteristics described in the previous paragraph or elsewhere herein. In some embodiments, the cartridge is prefilled with a predetermined volume of a liquid. A kit is also disclosed, which includes a plurality of the cartridges described above. In some embodiments, the kit also includes a pacifier apparatus, such as the ones described in the previous paragraph or elsewhere herein, which can be configured to couple to each of the plurality of cartridges individually and interchangeably.

In some embodiments of the apparatuses disclosed herein, the apparatus is configured to deliver a metered quantity of fluid. Some embodiments may be configured to expel fluid from the cavity through the nipple aperture at a desired, predetermined, and/or constant rate. For example, the apparatus of some embodiments is configured to expel fluid at an average rate of 0.0001 mL/s, the apparatus of other embodiments is configured to expel fluid at an average rate of 0.01 mL/s, and the apparatus of other embodiments is configured to expel fluid at an average desired rate therebetween, when sucked by a neonate and/or when the pump is squeezed. Additionally, in many but not all embodiments, the apparatus is disposable and/or adapted for one-time use.

The nipple base of various embodiments may be overmolded and the proximal face and the distal face may be curved proximally inward so as to be adapted to fit the curvature of a face. In some embodiments, a center height of the proximal face is shorter than an edge height of the proximal face, and a center height of the distal face is shorter than an edge height of the distal face. With such a configuration, the nipple base has a shape adapted to provide space between the nipple base and a child's nose when the nipple is positioned within a child's mouth. In some embodiments, the nipple base further includes a plurality of through-holes configured to allow the passage of air between the distal face and the proximal face. In some embodiments, these through-holes securely but reversibly retain a plug disposed on a strap, and the strap is fixedly connected to the nipple base. The strap of such embodiments is flexible so as to allow for movement of the plug between a through-hole and a distal opening of a receiving tube.

In various embodiments, the nipple aperture is in the form of a slit or a hole. In some embodiments, the nipple aperture is positioned on the proximal tip of the nipple; in other embodiments, the nipple aperture is positioned elsewhere on the proximal end of the nipple, for example, on the bulbous portion of the nipple, offset from the proximal tip. Such an offset may mitigate choking of fluid and gag reflex. In some embodiments, the distal opening to the cavity is in the form of a slit, hole, valve, or frangible seal.

Additionally, systems for administering fluid are disclosed herein. In one embodiment, the system includes: a pacifier apparatus configured for administering fluid, such as the apparatuses described herein; a fluid stored within the cavity, wherein the fluid has a known volume; and a sterile packaging unit surrounding the apparatus. In one particular embodiment, the fluid includes 2 mL of sucrose solution. In other embodiments, different volumes and/or different fluids are used. In some embodiments, the fluid includes one or more of a probiotic formula, a vitamin formula, a nutritive formula, breast milk, colostrum, sweetened water or other fluid, an anti-gas fluid (e.g., simethicone (Mylicon®)), or a liquid medication. In another embodiment of the system, the system includes a pacifier apparatus configured for administering fluid as disclosed herein, a liquid-filled gel capsule positioned within the cavity, and a sterile packaging unit surrounding the apparatus. In such an embodiment, a coating of the liquid-filled gel capsule may be configured to dissolve when subjected to a known environmental trigger, such as, for example, heat sterilization, to release fluid into the cavity. In an additional embodiment, the fluid or liquid-filled gel capsule is replaced with a powder stored within the cavity, wherein the powder has a known mass and is configured to dissolve in water. In some embodiments, the powder includes a lyophilized solution. The entire system of some embodiments is configured for one-time use.

In various embodiments of the system, the sterile packaging unit may include, for example, a shell having a distal shell member, a proximal shell member, and an attachment element configured to detachably connect the distal shell member and the proximal shell member. Moreover, the shell of some embodiments has an inner surface, an outer surface, and a plurality of anchor arms extending from the inner surface into an interior of the shell. The plurality of anchor arms are configured to secure the apparatus in a stable position inside the shell, for example, by engaging with a plurality of through-holes located in the nipple base. In some embodiments, the attachment element includes a pull seal configured to wrap substantially around a circumference of the shell and a pull-tab affixed to an end of the pull seal. The pull seal is configured to fixedly couple the distal shell member to the proximal shell member until the pull-tab is pulled and the pull seal is removed. The pull seal of some embodiments is attached to a proximal end of the distal shell member and a distal end of the proximal shell member via a perforated connection. The sterile packaging unit may additionally include a double-sided adhesive pad positioned on the inner surface, which is configured to contact the nipple aperture and seal it closed while positioned in the packaging unit. In the alternative, the sterile packaging unit may include, for example, a stub anchor extending from the inner surface into an interior of the shell, which is configured for insertion into the nipple aperture to prevent fluid from leaking.

In some embodiments, one or more of the systems and/or components, as described herein, are packaged together to form a kit. In one embodiment, the kit includes a plurality of systems having a plurality of age-specific nipple sizes. In some such embodiments, the nipples within the kit each have an age-specific nipple aperture size. The nipples of the apparatuses within the kit are selected such that the sizes are tailored to cover a spectrum of age groups. The kits of some

embodiments further include an outer packaging container. In other embodiments, the kits may include, for example, an apparatus as described herein and one or more medicaments that can be used with the apparatuses, or an apparatus and a cartridge that is configured to be inserted in and used with the apparatus. Some embodiments described in more detail herein relate to the cartridges of medicaments or fluids themselves.

Another system for administering fluid is disclosed which includes a pacifier apparatus, such as the apparatuses described above, a breast pump, and a mechanism to, or means of, connecting the breast pump directly or indirectly to at least a portion of the pacifier apparatus. In some embodiments, the breast pump can be coupled directly or indirectly to the nipple of the pacifier apparatus such that breast milk or colostrum can be pumped through the nipple aperture and into the nipple cavity. In other embodiments, the breast pump can be coupled directly or indirectly to the nipple base, one or more receiving tubes disposed within the nipple, and/or the pump of the pacifier apparatus, such that milk or colostrum can be pumped through an opening in the nipple base or an opening in the pump of the pacifier apparatus. In still other embodiments, the breast pump can be coupled directly or indirectly to a cartridge configured for insertion into a pacifier apparatus. In various embodiments, the mechanism to, or manner of, connecting the breast pump to at least a portion of the pacifier apparatus includes, for example, tubing, piping, a valve, funnel, blunt tip needle, or other conduit for directing the flow of fluids. It should be understood that in some embodiments, the fluid can be extracted from the mother by the breast pump and then transferred to a device or apparatus as described herein via any suitable method. For example, the fluid in the breast pump can be transferred by pouring, via a syringe, via syringe and needle, via a pump, via tubing and gravity, etc.

Some embodiments relate to methods of manufacturing a pacifier apparatus configured for administering fluid. In one embodiment, the method includes, for example, positioning a distal mouth of a balloon around at least a proximal portion of a rigid member such that an air passage exists between a body of the balloon and a hole located on a distal portion of the rigid member or on a pump coupled to the distal portion of the rigid member. The method of some embodiments also includes, for example, permanently affixing the distal mouth of the balloon to at least the proximal portion of the rigid member, and vacating air from the air passage to retract the balloon into an undeployed state. Additionally, the method of some embodiments includes forming a unitary pacifier body, wherein the pacifier body includes a nipple base and a nipple. The nipple base has, for example, a proximal face, a distal face, and a passage extending through the nipple base. The nipple extends proximally outward from the proximal face and includes, for example, a nipple wall, which defines a cavity. In some embodiments, the method further includes securely affixing the balloon mouth and at least the proximal portion of the rigid member to the passage wall, forming a nipple aperture through a proximal tip of the nipple wall, vacating air from the cavity, and filling the cavity with a predetermined volume of fluid. The method may additionally include sealing the nipple aperture temporarily so as to prevent fluid from spilling from the cavity.

In some embodiments, forming a nipple aperture includes, for example, making a slit in or near the proximal tip of the nipple wall. In other embodiments, forming a nipple aperture includes, for example, puncturing a hole in or near the proximal tip of the nipple wall. In some embodiments, filling the cavity with a desired volume of fluid includes, for example, injecting the known volume of fluid into the cavity through the nipple aperture. In other embodiments, filling the cavity with a known volume of fluid includes, for example, squeezing the pump, inserting the nipple aperture into a fluid, releasing the pump, and removing the nipple aperture from the fluid when a desired quantity of the fluid has entered the cavity. Vacating air from the cavity includes, for example, vacuuming air from the cavity through the nipple aperture. In other embodiments, vacating air from the cavity includes, for example, expelling air from the nipple aperture by forcing air into the air passage so as to transition the balloon into a fully deployed state. In some embodiments of the method, the step of vacating air from the cavity by forcing air into the air passage may be performed before the step of vacating air from the air passage to retract the balloon into an undeployed state, for example. In other embodiments, the steps may be performed in any desired and/or logical order. In some embodiments, permanently affixing the balloon mouth to at least the proximal portion of the rigid member includes, for example, applying an adhesive between the balloon mouth and the rigid member. In other embodiments, the step includes, for example, fusing the balloon mouth to the rigid member using ultrasonic welding. In still other embodiments of the method, the step includes, for example, fixating an outer locking ring around the balloon mouth after it has been positioned around at least the proximal portion of the rigid member.

In an additional embodiment for a method of manufacture, the method includes, for example: molding a unitary pacifier body comprising (1) a nipple base comprising a proximal face, a distal face, and a passage wall defining a passage extending through the nipple base, and (2) a nipple extending proximally outward from the proximal face and having a nipple wall which defines a cavity; forming a nipple aperture through the nipple wall in or near the proximal tip; inserting a balloon through the passage and into the cavity with the balloon in a deployed state; inserting a proximal end of a rigid member into a distal mouth of the balloon such that the rigid member is fixedly coupled directly or indirectly to the passage wall upon insertion; and filling the cavity with a known volume of fluid. In some embodiments, the rigid member is tapered to facilitate insertion into the distal mouth of the balloon.

In an additional embodiment of a method of manufacturing a pacifier apparatus, the method includes, for example: molding a unitary nipple assembly comprising (1) a nipple base comprising a proximal face, a distal face, and a passage wall defining a passage extending through the nipple base, and (2) a nipple extending proximally outward from the proximal face and having a nipple wall which defines a cavity; forming a nipple aperture through a proximal tip of the nipple wall; inserting a receiving tube into the cavity and/or molding the nipple so that the cavity is configured to form a receiving tube, wherein the receiving tube is sized and shaped to securely receive a proximal portion of a fluid-filled cartridge. The receiving tube of some embodiments may have various non-uniform diameters along the length of the receiving tube to control the rate of fluid flow by creating high and low pressure channels. In some embodiments, the method may include inserting or forming a plurality of receiving tubes within the nipple of the pacifier. In other embodiments, the method may include molding a valve into the receiving tube to occlude air ingestion until acted upon by a force. In some embodiments, the method also includes molding or attaching a strap with a plug to a nipple base. In one embodiment of using such an apparatus, the method includes removing a seal from the

cartridge aperture of the cartridge, inserting a proximal portion of the cartridge into the receiving tube of a nipple assembly, inserting a nipple of the nipple assembly into the mouth of an individual, and actuating the cartridge by deforming a distal portion of the cartridge such that a liquid flows from a reservoir of the cartridge, through the cartridge aperture, through the nipple aperture, and into the mouth of the individual. In some embodiments, a plug can be placed into a through-hole of the nipple base so that the plug is out of the way when the cartridge is coupled to the receiving tube, and the plug can be positioned within a distal end of the receiving tube once the cartridge has been removed. In some embodiments, positioning the plug within the distal end of the receiving tube limits the individual's ingestion of air as they suck on the nipple of the nipple assembly.

A method of manufacturing an age-specific pacifier apparatus configured to administer fluids is also disclosed. In some embodiments, the method includes: determining an average number of sucks performed in a defined length of time by patients of a pre-defined age group; determining a desired length of fluid administration; determining a desired volume of fluid to be administered; calculating an optimum flow rate by dividing the desired volume by the desired length of fluid administration and performing a unit conversion step if necessary; calculating an optimum volume of fluid expelled per suck by dividing the optimum flow rate by the average number of sucks performed in a defined length of time and performing a unit conversion step if necessary; selecting a desired nipple wall thickness, a desired nipple wall density, a desired cavity volume, a desired nipple aperture size, and a desired size of a distal cavity opening, which are together configured to achieve a desired average pressure change within the nipple during a suck and thereby achieve the optimum volume of fluid expelled per suck; molding a pacifier apparatus comprising a base and nipple from a polymeric material, wherein the nipple is molded to have the desired nipple wall thickness and the desired nipple wall density, and wherein the cavity is sized to hold the desired volume of fluid; and puncturing a proximal tip of the nipple to create a nipple aperture having the desired nipple aperture size and a distal end of the pacifier apparatus to create a distal cavity opening having the desired distal cavity opening size. Some embodiments of the method further include filling the cavity with the desired volume of fluid to be administered. The fluid may be filled through the nipple aperture or the distal cavity opening. In other embodiments, the size, shape, strength, and/or position of a receiving tube and/or nipple aperture are selected to achieve a desired angle of fluid expulsion or a desired rate of fluid expulsion when a given negative pressure is applied to the nipple.

A method of providing comfort to a child is also described. In various embodiments of the method, the child may be positioned at any angle. The method includes, for example, providing a pacifier apparatus as described herein to a child that is positioned at any angle, wherein the apparatus includes, at least, a pump or actuatable cartridge, a nipple, and a nipple aperture. A fluid is stored within a nipple cavity or a cartridge reservoir. The apparatus of some embodiments also includes a balloon. The method further includes inserting the apparatus into the child's mouth for sucking, wherein sucking and/or actuating the pump or cartridge causes at least a portion of the fluid to flow from the cavity or reservoir through the nipple aperture and into the mouth. In some embodiments, sucking causes the balloon to gradually transition from an at least partially or substantially undeployed state to a substantially deployed state in which the balloon is positioned in the cavity and forms the general shape of the nipple upon deployment. Additionally, if the child does not suck on the nipple or does not suck forcefully enough, for example, to transition the balloon into the deployed state, the method may include actuating the pump or cartridge to expel fluid from the cavity or reservoir into the child's mouth. In some embodiments, actuating the pump transitions the balloon into the deployed state, which thereby expels the fluid from the cavity.

In an additional embodiment, the method of providing comfort to a child includes providing a pacifier apparatus filled with solution, wherein the apparatus is structured in accordance with any of the embodiments disclosed herein, positioning the apparatus into the mouth of a child so that the child can suck on the apparatus and thereby cause the solution to flow from the apparatus, and if necessary and/or desired, manipulating a pump on the device in order to expel the solution into the mouth of the child if the child does not suck on the device or if the sucking of the child is insufficient to cause a desired amount of solution to flow from the apparatus. In some embodiments, the pump used within the method is, for example, a depressible pump. various embodiments, the comfort provided to the child can be one or more of soothing the child and providing a medicament to the child, for example. In some embodiments, the solution includes, for example, one or more of a sweetened solution, a medicament, water, baby formula, breast milk, colostrum, or any other fluid as described herein or otherwise desired. In accordance with various embodiments of the method, the child may be positioned so as to be at an angle of between about 0 degrees and 180 degrees relative to horizontal. Embodiments are conceived in which the child receives the apparatus while undergoing a medical procedure or examination or when otherwise agitated or upset. The methods can include providing comfort or treatment of a child or patient suffering from or going through an illness, discomfort, or a medical treatment or procedure. For example, the discomfort may be caused by gas, an upset stomach, an injury, or any other cause. The medical treatment or procedure can be one or more of circumcision, receiving a shot, a blood prick or puncture, a diagnostic examination, etc. The illness can be a fever, a cold, a flu, etc.

BRIEF DESCRIPTION OF THE DRAWINGS

The above-mentioned features, as well as other features, aspects, and advantages of the present technology will now be described in connection with various embodiments of the invention, in reference to the accompanying drawings. The illustrated embodiments, however, are merely examples and are not intended to limit the invention.

FIG. **1**A depicts an exploded side view of one embodiment of a pacifier apparatus configured for the oral administration of fluids.

FIG. **1**B depicts a perspective view of the embodiment illustrated in FIG. **1**A.

FIG. **1**C depicts a distal view of the embodiment illustrated in FIG. **1**A.

FIG. **1**D depicts a cross-sectional view of the embodiment illustrated in FIG. **1**A. The selected viewing angle of the cross-section is identified in FIG. **1**C.

FIG. **2**A depicts an exploded side view of a second embodiment of a pacifier apparatus configured for the oral administration of fluids. The exploded view includes depictions of a rigid member assembly, a balloon, and a nipple assembly.

FIG. **2**B depicts a distal view of the embodiment illustrated in FIG. **2**A.

FIG. 2C depicts a cross-sectional view of the embodiment illustrated in FIG. 2A. The selected viewing angle of the cross-section is identified in FIG. 2B.

FIG. 2D depicts a distal view of one embodiment of a rigid member assembly with a balloon affixed to the rigid member assembly.

FIG. 2E depicts a cross-section of the rigid member assembly and the balloon illustrated in FIG. 2D.

FIG. 3A depicts a perspective view of an embodiment of a pacifier apparatus configured for the oral administration of fluids, wherein the apparatus includes a pump.

FIG. 3B depicts a side view of another embodiment of a pacifier apparatus configured for the oral administration of fluids, wherein the apparatus includes a pump in the form of a syringe.

FIG. 4A depicts a perspective view of another embodiment of a pacifier apparatus configured for the oral administration of fluids and having a pump.

FIG. 4B depicts a distal view of the embodiment illustrated in FIG. 4A.

FIG. 4C depicts a cross-sectional view of the embodiment illustrated in FIG. 4A with a balloon in an undeployed state. The selected viewing angle of the cross-section is identified in FIG. 4B.

FIG. 4D depicts a cross-sectional view of the embodiment illustrated in FIG. 4A with a balloon in a semi-deployed state. The selected viewing angle of the cross-section is identified in FIG. 4B.

FIG. 4E depicts a cross-sectional view of the embodiment illustrated in FIG. 4A with a balloon in a fully deployed state. The selected viewing angle of the cross-section is identified in FIG. 4B.

FIG. 5A depicts an exploded side view of another embodiment of a pacifier apparatus configured for the oral administration of fluids.

FIG. 5B depicts a perspective view of the embodiment illustrated in FIG. 5A.

FIG. 5C depicts a distal view of the embodiment illustrated in FIG. 5A.

FIG. 5D depicts a cross-sectional view of the embodiment illustrated in FIG. 5A. The selected viewing angle of the cross-section is identified in FIG. 5C.

FIG. 6A depicts an exploded side view of another embodiment of a pacifier apparatus configured for the oral administration of fluids.

FIG. 6B depicts a distal view of the embodiment illustrated in FIG. 6A.

FIG. 6C depicts a cross-sectional view of the embodiment illustrated in FIG. 6A. The selected viewing angle of the cross-section is identified in FIG. 6B.

FIG. 7A depicts an exploded side view of another embodiment of a pacifier apparatus configured for the oral administration of fluids.

FIG. 7B depicts a distal view of the embodiment illustrated in FIG. 7A.

FIG. 7C depicts a cross-sectional view of the embodiment illustrated in FIG. 7A. The selected viewing angle of the cross-section is identified in FIG. 7B.

FIG. 8A depicts an exploded side view of another embodiment of a pacifier apparatus configured for the oral administration of fluids.

FIG. 8B depicts a perspective view of the embodiment illustrated in FIG. 8A.

FIG. 8C depicts a distal view of the embodiment illustrated in FIG. 8A.

FIG. 8D depicts a cross-sectional view of the embodiment illustrated in FIG. 8A. The selected viewing angle of the cross-section is identified in FIG. 8C.

FIG. 9A depicts an exploded side view of another embodiment of a pacifier apparatus configured for the oral administration of fluids.

FIG. 9B depicts a distal view of the embodiment illustrated in FIG. 9A.

FIG. 9C depicts a cross-sectional view of the embodiment illustrated in FIG. 9A. The selected viewing angle of the cross-section is identified in FIG. 9B.

FIG. 10A depicts a perspective view of another embodiment of a pacifier apparatus configured for the oral administration of fluids.

FIG. 10B depicts a distal view of the embodiment illustrated in FIG. 10A.

FIG. 10C depicts a cross-sectional view of the embodiment illustrated in FIG. 10A. The selected viewing angle of the cross-section is identified in FIG. 10B.

FIG. 11A depicts a perspective view of another embodiment of a pacifier apparatus configured for the oral administration of fluids.

FIG. 11B depicts a distal view of the embodiment illustrated in FIG. 11A.

FIG. 11C depicts a cross-sectional view of the embodiment illustrated in FIG. 11A. The selected viewing angle of the cross-section is identified in FIG. 11B.

FIG. 12A depicts an exploded side view of an embodiment of a pacifier system configured for the oral administration of fluids.

FIG. 12B depicts a perspective view of the embodiment illustrated in FIG. 12A.

FIG. 12C depicts a distal view of the embodiment illustrated in FIG. 12A.

FIG. 12D depicts a cross-sectional view of the embodiment illustrated in FIG. 12A. The selected viewing angle of the cross-section is identified in FIG. 12C.

FIG. 13A depicts a perspective view of one embodiment of a pacifier system that includes a nipple assembly and a cartridge.

FIG. 13B depicts a bottom/distal view of the embodiment shown in FIG. 13A.

FIG. 13C depicts a cross-sectional view of the embodiment of FIG. 13A. The selected viewing angle of the cross-section is identified in FIG. 13B.

FIG. 14A depicts a perspective view of the nipple assembly embodiment included in FIG. 13A.

FIG. 14B depicts a top/proximal view of the nipple assembly embodiment of FIG. 14A.

FIG. 14C depicts a bottom/distal view of the nipple assembly embodiment of FIG. 14A.

FIG. 14D depicts a cross-sectional view of the nipple assembly embodiment of FIG. 14A. The selected viewing angle of the cross-section is identified in FIG. 14C.

FIG. 15A depicts a perspective view of another embodiment of a nipple assembly.

FIG. 15B depicts a top/proximal view of the nipple assembly embodiment of FIG. 15A.

FIG. 15C depicts a bottom/distal view of the nipple assembly embodiment of FIG. 15A.

FIG. 15D depicts a cross-sectional view of the nipple assembly embodiment of FIG. 15A. The selected viewing angle of the cross-section is identified in FIG. 15C.

FIG. 16A depicts a front view of the cartridge embodiment included in FIG. 13A.

FIG. 16B depicts a side view of the cartridge embodiment of FIG. 16A.

FIG. **16**C depicts a perspective view of the cartridge embodiment of FIG. **16**A.

FIG. **16**D depicts a perspective view of the cartridge embodiment of FIG. **16**A with a seal removed.

FIG. **16**E depicts a side view of the cartridge embodiment of FIG. **16**A with a seal removed.

FIG. **16**F depicts a front view of the cartridge embodiment of FIG. **16**A with a seal removed.

FIG. **17**A depicts a perspective view of another embodiment of a nipple assembly configured to receive a cartridge.

FIG. **17**B depicts a top/proximal view of the nipple assembly embodiment of FIG. **17**A.

FIG. **17**C depicts a bottom/distal view of the nipple assembly embodiment of FIG. **17**A.

FIG. **17**D depicts a cross-sectional view of the nipple assembly embodiment of FIG. **17**A. The selected viewing angle of the cross-section is identified in FIG. **17**C.

FIG. **17**E depicts another perspective view of the nipple assembly embodiment of FIG. **17**A.

FIG. **18** is a perspective view of another embodiment of a nipple assembly configured to receive a cartridge.

FIG. **19**A depicts a perspective view of one embodiment of a sterile packaging unit for any of the apparatuses disclosed herein.

FIG. **19**B depicts an exploded view of one embodiment of a system, which includes an apparatus configured for the oral administration of fluids and a sterile packaging unit.

FIG. **19**C depicts a perspective view of one embodiment of a proximal portion of a sterile packaging unit.

FIG. **19**D depicts a distal view of one embodiment of a sterile packaging unit.

FIG. **19**E depicts a cross-sectional view of the sterile packaging unit embodiment illustrated in FIG. **13**D.

FIG. **20**A depicts a perspective view of an embodiment of a bulk shipping configuration for the sterile packaging units disclosed herein.

FIG. **20**B depicts a distal view of the bulk shipping configuration embodiment illustrated in FIG. **14**A.

FIG. **20**C depicts a cross-sectional view of the bulk shipping configuration embodiment illustrated in FIG. **14**B.

FIG. **21** depicts a perspective view of an embodiment of a method of assembling one embodiment of a pacifier apparatus configured for the oral administration of fluids.

FIG. **22** depicts a perspective view of an embodiment of a nipple assembly configured for the oral administration of fluids.

FIG. **23**A depicts a perspective view of an embodiment of a pacifier system that includes a nipple assembly and a cartridge.

FIG. **23**B depicts a cross-sectional view of the nipple assembly embodiment of FIG. **23**A.

DETAILED DESCRIPTION OF CERTAIN EMBODIMENTS

In the following detailed description, reference is made to the accompanying drawings, which form a part of the present disclosure. In the drawings, similar symbols typically identify similar components, unless context dictates otherwise. The illustrative embodiments described in the detailed description, drawings, and claims are not meant to be limiting. The detailed description is intended as a description of exemplary embodiments and is not intended to represent the only embodiments which may be practiced. The term "exemplary," as used herein, means "serving as an example, instance, or illustration," and should not necessarily be construed as preferred or advantageous over other embodiments. Other embodiments may be utilized, and other changes may be made, without departing from the spirit or scope of the subject matter presented here. It will be readily understood that the aspects of the present disclosure, as generally described herein, and illustrated in the Figures, can be arranged, substituted, combined, and designed in a wide variety of different configurations, all of which are explicitly contemplated and form part of this disclosure.

As noted above, embodiments described herein generally relate to apparatuses, systems, and methods of administering fluids or medical instrumentation to a patient, such as, for example, an infant child. One or more of the provided embodiments may overcome one or more of the drawbacks, limitations, or deficiencies that exist in the inpatient and outpatient markets. For example, in some embodiments, the apparatuses are single use, disposable, pre-loaded with a desired substance, configured to dispense a desired amount of fluid over a given period of time, and configured to dispense fluid upon actuation. In some embodiments, the apparatuses are actuated via sucking by the patient and/or pumping or squeezing by a care giver. In some embodiments, the apparatuses, systems, kits, and methods provide a more simple, efficient, and safe device for fluid administration. In some embodiments, the apparatuses are configured to receive and couple to various medical accessories to facilitate oral administration of medical instruments, when needed. The description herein provides examples of the apparatus, systems, kits, and methods according to various non-limiting embodiments.

FIGS. **1**A-**1**D illustrate a pacifier apparatus **100** in accordance with one embodiment of the present technology. FIG. **1**A depicts an exploded side view of the embodiment, while FIG. **1**B provides a perspective view, FIG. **1**C provides a distal view, and FIG. **1**D provides a cross-sectional view of the same embodiment. The apparatus **100** includes a rigid member assembly **110**, a balloon **120**, and a nipple assembly **130**, as shown in the exploded view of FIG. **1**A. The nipple assembly **130** of various embodiments includes a nipple base **132** and a nipple **134**. The nipple base **132** as depicted includes a distal face **131** and a proximal face **133**. The nipple **134** extends proximally from the proximal face **133** and includes a nipple wall **135** that defines a cavity **137** configured to hold fluid. The cavity **137** may be configured to hold any desired fluids, such as, for example, sucrose solutions and other analgesics, probiotic cultures, vitamins, nutritive solutions, colostrum, breast milk, antibiotics, anti-gas, over-the-counter medicaments, other liquid medicaments, and other fluids. The cavity **137** also may be configured to hold solution precursors, such as fluid-filled gel capsules and powders, which form a fluid solution upon exposure to the proper environmental trigger, such as, for example, heat and water, respectively.

In various embodiments, the nipple **134** is configured for sucking, such as within the mouth of a neonate or infant. As shown in FIGS. **1**C and **1**D, an air opening **104** is located at a distal end **101** of the apparatus **100**. It should be understood that the air opening **104** can be located at any desirable location, not just the depicted location, and it can be of any suitable size and geometry. In some embodiments, the air opening **104** is configured to permit air or other gases to enter the chamber to prevent or minimize vacuum formation, wherein vacuum formation can prevent fluid from flowing out of the nipple aperture **136**. The nipple aperture **136** is located at a proximal end **102** of the apparatus **100**. In some embodiments, the configuration is designed to enable expulsion of fluid from the cavity **137** through the nipple aperture **136** and into the mouth of the neonate or

infant, upon the nipple **134** being sucked. To facilitate sucking and fluid expulsion, in some embodiments, the nipple **134** is formed of a resilient and flexible material, including for example, one that is capable of non-permanent deformation. In one embodiment, the nipple **134** is formed of silicone. In other embodiments, the nipple **134** is formed of one or more of latex, plastic, rubber, another polymer, or a composite of polymers.

In some embodiments, the material characteristics of the nipple wall **135** and the size of the cavity **137** are carefully and purposefully selected. For example, in some embodiments, the cavity **137** is configured to hold a pre-determined volume of fluid. The cavity **137** can be configured to hold, for example, a recommended or desired dose of a medicament or fluid. The cavity **137** of some embodiments is sized to optimally hold, for example, 0.5-25 mL of fluid, or any individual value or sub-range therebetween. Additionally or alternatively, in some embodiments, the nipple size is tailored during the manufacturing process to comfortably fit within the average mouth size of a particular age group. Additionally, or in the alternative, in some embodiments, the thickness and flexibility of the nipple **134** and the size of the air opening **104** and the nipple aperture **136** are selected to form an apparatus **100** having a controlled flow rate of a predetermined value. As used herein, an apparatus can be said to have a controlled flow rate of a predetermined value if a fluid of a pre-selected viscosity flows from the nipple aperture **136** at a relatively steady average rate when subjected to a desired and constant rate of sucking, wherein each suck exerts a desired and constant force. For example, the size and material characteristics may be selected such that the apparatus **100** achieves an average flow rate that is most suitable for the fluid being administered, when the apparatus **100** is provided to an individual who sucks on the apparatus **100** with the same rate and force as an average child of an intended age group. The selected flow rate may be procedure-specific and/or age-specific, varying based on the fluid viscosity, recommended dose, and the average strength and rate of sucking performed by individuals in a target age group.

In one embodiment, such as the embodiment of FIGS. **1**A-**1**D, the nipple **134** and nipple base **132** are integrally formed as a unitary body. In other embodiments, the nipple **134** and nipple base **132** are formed separately and fused or otherwise affixed together during the manufacturing or use process.

When the apparatus **100** is fully assembled, the balloon **120**, depicted in FIG. **1**A, can be located in a passage within the nipple base **132** and/or within the cavity **137**. The balloon **120** of some embodiments is configured to transition from an undeployed or partially undeployed state to a deployed state or a nearly deployed state when the nipple **134** is sucked or squeezed. In a fully deployed state, the balloon **120** of some embodiments has an exterior size that is more or less the same size as the interior of the nipple wall **135**. Thus, in the fully deployed state, the balloon **120** substantially lines the interior of the nipple wall **135**. By transitioning towards a deployed state in response to the nipple **134** being sucked or squeezed, the deploying balloon **120** exerts force onto the fluid within the cavity **137**, facilitating expulsion of the fluid from the cavity **137** through the nipple aperture **136**. The directional force created by the balloon **120** filling into the cavity **137**, guides fluid towards the nipple aperture **136** regardless of the angle of the apparatus **100** or the user of the apparatus. Therefore, in such embodiments, fluid can be administered to an infant or child situated in any position, for example from 0 to 180 degrees from horizontal, that is, from laying horizontally to sitting or even leaning forward. Furthermore, in the deployed state, the balloon **120** effectively can at least partially or completely line and seal the cavity **137**, thereby preventing air from flowing from the air opening **104** through the nipple aperture **136**. In this manner, the apparatus **100** can be configured to limit a user's ingestion of air. The balloon **120** of various embodiments is formed, for example, from one or more of the following: a balloon, a sock, a sleeve, a bag, and any other membrane configured to transition from a limp, substantially undeployed state to an expanded, substantially deployed state that substantially lines the interior of the nipple wall **135**. In some embodiments, the balloon **120** is made of one or more of latex, low density polyethylene, other plastic or polymeric material, or any other suitable material. Moreover, while an apparatus having a balloon is described here and elsewhere in the specification, it should be understood that an appropriate equivalent to the balloon **120**, and one contemplated here, is any element adapted to move proximally within the cavity **137** in response to negative pressure being created in the cavity from sucking and/or in response to positive pressure being exerted on the element from a distal direction, such as, for example when a pump (described in detail below) is actuated. As one illustrative example, a slideable solid material, such as a stopper or plunger, may be used to perform the same function as the balloon **120** described herein.

It should be understood that the term "substantially undeployed can mean that the device is not more than 30% deployed, preferably less than 20%, less than 10%, less than 5%, less than 3%, 2%, or 1% deployed, or any value or subrange therein. The term "substantially deployed" can mean for example, that the device is from about 60% to 99.9% (or even 100%) deployed or any sub-range or value there between, for example, preferable at least 70%, 80%, 90%, 95%, 96%, 97%, 98%, or 99% deployed. Furthermore, the term "substantially line" can mean that the device lines from 60%-100% of the interior of the nipple or any subrange or value there between, for example, at least 70%, 80%, 90%, 95%, 96%, 97%, 98%, or 99%.

As shown in FIG. **1**D, the embodiment of FIG. **1** also may include a passage wall **138** that defines a passage extending through the nipple base **134** from the distal face **131** to the proximal face **133**. In several embodiments, the passage may be centrally located in the nipple base **132** and axially aligned with a distal opening to the cavity **137**. Such a configuration allows for the positioning of a rigid member **112** within the passage and the positioning of a mouth **122** of the balloon **120** around the rigid member **112** with the body **124** of the balloon **120** then able to extend into the cavity **137** of the nipple assembly **130**.

In the depicted embodiment, the rigid member **112** (see, e.g., FIG. **1**A) extends into the passage of the nipple base **132** is provided to secure the balloon mouth **122** in a fixed position relative to the nipple base **132**. In some embodiments, a rigid member assembly **110** is also provided to help secure the rigid member **112**, and ultimately, the balloon **120** relative to the nipple base **132**. The rigid member assembly **110** can take many forms. In some embodiments, such as the one illustrated in FIG. **1**A-**1**D, the rigid member **112** is integrally connected to, and extends proximally from, a rigid plate **111**.

In some embodiments, the rigid plate **111** has a handle **116** extending distally from the rigid plate **111**. Such a handle **116** as depicted is configured to extend away from a user's face when the apparatus **100** is positioned within a user's

mouth in order to facilitate insertion and removal of the apparatus **100** by the user or the user's caregiver. The handle **116** also can be positioned in other locations and/or directions. In the embodiment of FIG. **1**A-**1**D, the rigid plate **111** is positioned on the distal face **131** of the nipple base **132** and fixedly attached to the nipple base **132** through, at least, the use of one or more anchors **114**. Such anchors **114** extend proximally from the rigid plate **111** through anchor holes located within the nipple base **132**. The anchors may be in any desired configuration, for example, the depicted mushroom-shape, and they optionally can include threaded members having a screw head, or be of any other design that creates a secure connection between the nipple base **132** and the rigid member assembly **110**. In addition or in the alternative, the anchors **114** may extend distally from the distal face **131** of the nipple base **132** through anchor holes located within the rigid plate **111**. The anchors **114** may provide for a press fit, snap fit, screw fit, or any other desired connection.

In some embodiments, such as the apparatus embodiment depicted in the exploded view of FIG. **2**A, no anchors are present. Anchors are not necessary, for example, if the rigid member **112** and balloon mouth **122** are secured relative to the nipple base **132** through other fixation means. As illustrated in FIGS. **2**B and **2**C, which respectively depict a distal view and cross-sectional view of the embodiment of FIG. **2**A, the rigid member **112** and rigid plate **111** are secured to the nipple base **132** using another suitable or desired approach, for example, an interference fit, ultrasonic welding, use of a polymeric adhesive or other adhesive means, etc. Alternatively, in some embodiments, over-molding is used during the manufacturing process to secure at least a portion of the rigid member assembly **110** within the nipple base **132**. Similarly, as shown in the distal view and cross-sectional view of a balloon **120** coupled to a rigid member assembly **110**, provided in FIGS. **2**D and **2**E, respectively, the balloon **120** may be affixed to the rigid member **112** using any suitable fixation means. For example, in some embodiments, an industrial-strength adhesive or ultrasonic welding is used to secure the balloon.

In some embodiments, such as the ones illustrated in the perspective views of FIGS. **3**A, **3**B, and **4**A, the apparatus includes at least a nipple **134** and a nipple base **132**, as described above, and additionally, a pump **141**. The pump **141** serves as a primary or secondary mechanism for expelling fluid from the cavity **137** through the nipple aperture **136**. The pump **141** also can serve as a primary or secondary mechanism for deploying the balloon **120**, when such a balloon is present. It may be advantageous to provide a pump **141** on the distal end of the apparatus **100** to enable a caregiver to facilitate expulsion of the fluid. Such an embodiment may be particularly advantageous for administering fluid to premature neonates or others who cannot or are not sucking adequately. This configuration may also be advantageous during some procedures in which it is desirable to provide both light, fairly continuous flows of fluid, as is expressed during sucking, and larger aliquots of fluid administered at spaced intervals. In some embodiments, the apparatus with a pump is configured to provide metered (i.e., measured) doses of fluid. This configuration may be particularly advantageous in medical settings and other settings where a medicament is provided, as it is often extremely important to monitor the amount of medicament ingested. In some embodiments, the apparatus can expel a pre-measured amount, optionally at a measured flow rate. For example, in some embodiments, the apparatus is prefilled with a given amount or dosage of a fluid or product. During use of some such embodiments, the entire amount of pre-measured fluid or product may be expelled. In some such embodiments, the apparatus is configured to measure the amount of fluid expelled, such as for example, in instances where less than the total fluid in the apparatus is expelled. As an illustrative example, the apparatus may arrive filled with 5 mL of a fluid, but it may be desired that, for a particular infant, treatment, or procedure, only 3 mL be expelled. The apparatus of some embodiments is configured to provide a measurement of the expelled amount. For example, the apparatus of some embodiments includes measurement lines, such as, for example, the measurement lines **146** on the nipple **134** or on a syringe body **143**, which can be numbered and spaced to indicate the amount of fluid in, or expelled from, the device.

FIGS. **3**A, **3**B, and **4**A provide examples of pacifier apparatuses **100** having pumps **140**, for illustrative purposes only. The pump **141** of various embodiments may take any suitable, actuateable shape; for instance, as non-limiting examples, the pump may be bulbous, cylindrical, formed as a polyhedron, formed as a plunger, or formed as a syringe. Additionally, the pump **141** of various embodiments may be actuated in any desired way, for example, it can be compressible, depressible, and/or squeezable or can include any other appropriate pumping mechanism. In some embodiments, the pump **141** has an opening **104** positioned on a wall of the pump **141**; the opening **104** may be accompanied with ribs, grooves, concave or convex features, or any other form adapted to facilitate user identification of the location of the opening **104**. The opening **104** of some embodiments is formed as a hole, slit, valve, or any other shape which enables the flow of air into an interior of the pump **141**. As an example, the pump **141** in FIGS. **3**A and **4**A can be actuated by covering the opening **104** with a finger, squeezing the pump **141** to move the pump walls closer together and to thereby move at least some existing air from the pump into the balloon, and releasing or uncovering the opening **104** to allow air inflow, which enables the pump **141** to return to its initial size and state. In other embodiments, the pump **141** may be actuated by pushing down on a rigid and slideable, or non-rigid, top portion of the pump **141**. For example, in FIG. **3**B, the pump (i.e., syringe) **141** can be actuated by depressing the plunger **144** down at least partially into a syringe body **143**. Using a pump formed as a syringe, such as, for example, the syringe **141** of FIG. **3**B, may advantageously allow a caregiver to monitor the amount of fluid dispelled during use of the apparatus. For example, even though air rather than fluid is present in the syringe body **143** of various embodiments, a measured depression of the plunger **144** causes movement of air from the syringe body **143** into the balloon or nipple cavity, which translates into a comparable or nearly comparable level of fluid expulsion from the nipple cavity through the nipple aperture **136**.

FIG. **4**B provides a distal view of the pacifier apparatus **100**, including the pump **141**, depicted in FIG. **4**A. The pump **141** extends from the distal side of the apparatus such that a caregiver can easily reach and actuate the pump **141** to express fluid through the nipple aperture **136**.

FIGS. **4**C-**4**E provide a cross-sectional view of the embodiment of FIGS. **4**A and **4**B. Each of FIGS. **4**C-**4**E depicts the same cross-sectional area and is provided to illustrate a balloon **120** transitioning from an undeployed (or substantially undeployed) state to a deployed (or substantially deployed) state. As shown in FIG. **4**C, in the undeployed state, the balloon **120** is limp and substantially retracted toward or into the passage or pump **141**. The depiction is not meant to be limiting; the balloon could be in

any orientation, for example, compacted in the same plane as the base **132**, etc. In response to the nipple **134** being sucked and/or the pump **141** being actuated, an undeployed balloon **120** will begin to transition toward a deployed state. A non-limiting depiction of a partially deployed balloon **120** is illustrated in FIG. **4**D. As shown in the figure, when in a partially deployed state, the balloon **120** partially enters the nipple cavity **137**. FIG. **4**E provides an illustration of a fully deployed balloon **120**. As visible in the illustration, in the fully deployed state, the balloon **120** is relatively comparable to the nipple wall **135** in size and shape. In such a state, the balloon **120** substantially lines an inner perimeter of the nipple wall **135**.

As with the non-limiting pump-less embodiments described above, in the embodiments that include a pump, there are numerous mechanisms for affixing or joining the various components together. Some embodiments that include a pump **141** also include a rigid member **112** designed to fixedly secure the balloon mouth **122** relative to the nipple assembly **130**. It should be understood that the rigid member can be a separate member or integral with some other component. In any case, the rigid member **112** is a component to which the balloon **120** can be attached in some embodiments. As illustrated in FIG. **5**A, the rigid member **112** of some embodiments is integrated into a rigid plate **111**. FIG. **5**A depicts an exploded view of one embodiment of a pacifier apparatus **100** having a pump **141**. FIGS. **5**B, **5**C, and **5**D depict the same embodiment through a perspective view, distal view, and cross-sectional view, respectively. In some embodiments, such as the one of FIGS. **5**A-**5**D, a second rigid member **113** is coupled to the rigid plate **111** such that one rigid member **113** extends distally and one rigid member **112** extends proximally from the rigid plate. Additionally, in some embodiments, such as the one of FIGS. **5**A-**5**D, the apparatus **100** further includes a pump base **142**. When present, the pump base **142** contains one or more through-holes **103** to allow for the passage of air from a distal side of the pump base **142** to a proximal side. Such through-holes **103** are also located in the nipple base **132** and the rigid plate **111**, when present in the apparatus **100**. The through-holes **103** in each element are positioned such that the through-holes of the various elements align and allow for the passage of air from a proximal side of the apparatus **100** to a distal side of the apparatus. The through-holes can function as a safety feature, helping to ensure that a child does not suffocate should the apparatus **100** become engulfed in the child's mouth or lodged in the child's airway. The pump as depicted in FIGS. **5** and **6** can be actuated for example by applying force or pressure to the pump **141** in the direction toward the base **142**, for example, while covering the hole **104**. Upon uncovering the hole **104**, the pump can return to its original position and can then be actuated again if desired.

The pump base **142** of some embodiments is integrally connected with a proximal end of the pump **141**. In the embodiment of FIGS. **5**A-**5**D, one rigid member **113** is positioned within a passage that extends through the pump base **142** and the other rigid member **112** is positioned within the passage that extends through the nipple base **132**. The nipple assembly **130**, rigid member assembly **110**, and pump assembly **140** are fixedly connected, for example, through the use of anchors **114**, **115**, some of which extend from a proximal face of the rigid plate **111** through holes located in the pump base **142** and some of which extend from a distal face of the rigid plate **111** through holes located in the nipple base **132**. In other embodiments, other means of connection may be used.

FIGS. **6**A-**6**C illustrate another embodiment of a pacifier apparatus **100** configured for the oral administration of fluid, which includes a pump **141**. FIG. **6**A provides an exploded view of the pump assembly **140**, rigid member assembly **110**, balloon **120**, and nipple assembly **130**, while FIGS. **6**B and **6**C provide a distal view and cross-sectional view, respectively, of the fully assembled apparatus **100**. The apparatus **100** of FIG. **6**A includes a pump **141**, which can be actuated, for example, by applying force or pressure to the pump **141** toward to the base **142** while covering the aperture **104**. Additionally or alternatively, the force can be provided by squeezing the pump **141** body to apply side or lateral pressure/force to the pump. In this illustrated embodiment, the rigid plate **111** of the rigid member assembly **110** lacks any anchors. Thus, the rigid plate **111** may be affixed to the pump assembly **140** and nipple assembly **130** by applying an industrial strength adhesive, performing ultrasonic welding, using over-molding, or through any other suitable fixation method.

In some embodiments of the pacifier apparatus **100**, such as the one illustrated in FIGS. **7**A-**7**C, the rigid member **112** extends proximally from the pump base **142**. Such a configuration may be present in designs where the rigid plate **111** is built or over-molded into the pump base **142**. Such a design is most visible in FIG. **7**C. Such a configuration may also be present in designs in which the rigid member **112** is integrally connected and formed with the pump base **142**. In such embodiments, the balloon **120** is affixed to the rigid member **112**, the rigid member **112** is affixed into the passage of the nipple base **132**, and the pump base **142** is directly coupled to the nipple base **132**. Previously mentioned fixation methods or any other suitable forms of fixation may be used. In some embodiments, the coupling of the nipple base **132** and pump base **142** is reinforced with the addition of anchors. The anchors may extend proximally from the pump base **142** for insertion through holes within the nipple base **132**. Additionally or in the alternative, anchors may extend distally from the nipple base **132** through holes within the pump base **142**. Similar to the apparatus **100** of FIG. **6**A, the apparatus **100** of FIG. **7** includes a pump **141**, which can be actuated by applying force to the pump **141**. The force can be applied by squeezing the sides together or by applying pressure toward the base in a proximal direction. If present, the aperture **104** can be covered in order to create pressure within the device.

FIGS. **8**A-**8**D illustrate an embodiment of a pacifier apparatus **100** having a modified pump assembly **140**. The pump assembly **140** of the depicted embodiment includes no pump base; instead, the rigid member **112** and anchors **114** extend directly from a proximal side of the pump **141**. In such an embodiment, the pump assembly **140** is securely fastened to the nipple assembly **130** by affixing the rigid member **112** to the passage wall of the nipple base **132** and by inserting the anchors **114** into anchor holes **139** in the nipple base **132**. In other embodiments, the anchors **114** may extend distally from the nipple base **132** for insertion into the pump **141**. The pump **141** of FIGS. **8**A-**8**D can be actuated, for example, by applying pressure or force to the pump **141**. The optional aperture **104**, if present, can be covered to allow internal pressure to be generated when the pump is pressed or squeezed, as desired.

An additional or alternative attachment mechanism is illustrated in the embodiment of FIGS. **9**A-**9**C. As shown in the exploded view of FIG. **9**A, a locking ring **150** is provided to reinforce attachment of the balloon **120** and rigid member **112** to the nipple base **132**. FIG. **9**B provides a distal view of the same embodiment. In this embodiment, the balloon

mouth **122** is positioned so as to engulf an outer perimeter of at least a proximal portion of the rigid member **112**. In an alternate embodiment, the balloon mouth **122** is affixed to an inner perimeter of a rigid member **112**. In either embodiment, the locking ring **150** is positioned around the rigid member **112**. The locking ring **150** may be positioned around a distal portion of the rigid member **112**, around the entire rigid member **112**, or around the balloon mouth **122** at a proximal portion of the rigid member **112**. The locking ring **150** is also securely attached to the nipple base **132** within the passage. In some embodiments, the locking ring **150** is integrally incorporated into the nipple assembly **130**, for example, in embodiments in which over-molding is used in the manufacturing process to build the nipple base **132** around the locking ring **150**.

As is visible in FIG. **9**A and the cross-sectional view of FIG. **9**C, in some embodiments, one of the rigid member **112** or locking ring **150** includes a groove, depression, indentation, or other recess (e.g., **117**) while the other of said rigid member **112** or locking ring **150** includes a ridge, ledge, protrusion or the like (e.g., **151**) configured to fit within the recess **117** in order to restrict movement of the rigid member **112** and balloon **120** in the distal and proximal directions. In addition or in the alternative, one of the rigid member **112** or locking ring **120** includes one or more tabs, teeth, or other protrusions (e.g., **118**) while the other of said rigid member **112** or locking ring **150** includes one or more slots or depressions each configured to receive a protrusion **118**. Such a feature may be included to limit the rotational movement of the rigid member **112** and balloon **120** relative to the nipple assembly **130**. In some embodiments, the rigid member **112** may be snapped or pressed into fixed engagement with the locking ring **150**. In other embodiments, the rigid member **112** and locking ring **150** may include complementary threading such that the rigid member **112** can be screwed into fixed engagement with the locking ring **150**. The pump **141** can be actuated as described elsewhere herein.

FIGS. **10**A-**10**C illustrate an additional embodiment of a pacifier apparatus **100** configured for the oral administration of fluid. As best shown in the cross-sectional view of FIG. **10**C, no attachment mechanisms are needed, because the apparatus **100** includes an integral, unitary body. For example, the apparatus can be made or manufactured by molding or any other suitable method to make such a unitary and/or integral apparatus. A perspective view and a distal view of this unitary body design are provided in FIGS. **10**A and **10**B, respectively. As is true for above-mentioned embodiments, the present embodiment includes, at least, a nipple **134**, a nipple base **132**, and a cavity **137** configured to hold fluid. In this embodiment, the cavity **137** is defined by both a nipple wall **135** and a portion of a proximal face **131** of the nipple base **132**, wherein said portion is enclosed by the nipple wall **135**. The cavity **137** of some embodiments is closed but for a nipple aperture **136** on a proximal tip of the nipple **134** and an optional opening **104** on a distal end of the cavity **137** which extends through the nipple base **132**. The opening **104**, if present, is configured to allow for the passage of air into the cavity **137** to enable sucking and/or to prevent the nipple wall **135** from collapsing.

In some embodiments, the opening **104** is in the form of a small pinhole or a slit. In some embodiments, the opening **104** includes a valve. In other embodiments, the opening **104** includes a frangible seal configured to seal fluid within the cavity **137** until the seal is ruptured just prior to use. The opening **104** may include any other form of hole or passage which is small enough to limit fluid from leaking from the opening during shipping and large enough to allow for sufficient passage of air. The opening **104** may be covered with a sticker or other removable seal to prevent fluid from spilling from the cavity during shipping. Such features of the optional opening **104** may be present in any of the pacifier apparatus embodiments and Figures described herein.

In various embodiments of the unitary apparatus, the size of the opening **104** and the size of the nipple aperture **136**, as well as the size of the cavity **137** and the thickness of the nipple wall **135** may be selected so that the apparatus **100** achieves a desired cavity pressure and a desired average flow rate when sucked on by an individual with an average sucking force and sucking rate equal to the average sucking force and sucking rate expected within the age group for which the apparatus **100** is tailored.

In some embodiments, such as the embodiment of FIGS. **10**A-**10**C, the apparatus has no removable parts. Such a pacifier apparatus **100**, which is capable of controlled flow while also having a unitary body design, may provide some advantages. The embodiment of FIGS. **10**A-**10**C is simple to manufacture, is low cost, and lacks potentially separable and therefore potentially hazardous parts. In some embodiments, such as the one depicted in FIGS. **10**A-**10**C, an optional handle **116** extends from the distal face **131** of the nipple base **132**. The handle **116** also may be part of the unitary body design.

In other embodiments of a pacifier apparatus **100** having a unitary design, such as the embodiment of FIGS. **11**A-**11**C, a pump **141** extends from the distal face **131** of the nipple base **132**. The pump of some embodiments includes one or more compressible walls **145**. As visible in the cross-sectional view of FIG. **11**C, in some embodiments having a unitary body with a pump **141**, the nipple wall **135** and compressible wall **145** each connect to a passage wall **138** in the nipple base **132**, and together, the nipple wall **135**, the compressible wall **145**, and the passage wall **138** define the cavity **137**. In some embodiments, the cavity **137** may constrict at the location of the nipple base **132**. As in above-mentioned embodiments of an apparatus **100** having a pump **141**, in the embodiment of FIGS. **11**A-**11**C, fluid can be expelled from a nipple aperture **136** at a proximal end of the nipple **134** by sucking or squeezing the nipple **134** and/or by compressing, depressing, or otherwise squeezing the pump **141**. The apparatus **100** having a unitary body may be formed of any suitable material, for example, one or more of silicone, plastic, rubber, or other polymer, composite, or material that is safe for children and non-permanently deformable.

An embodiment of a pacifier system is depicted in FIGS. **12**A-**12**D. As shown in the exploded view of FIG. **12**A, the pacifier system **1200** of the current embodiment includes: a pacifier apparatus in the form of a nipple assembly **130**, and an insertable cartridge **200**. The nipple assembly **130** includes a nipple **134** and a nipple base **132**. The nipple **134** extends proximally from the nipple base **132** and includes a nipple wall **135**, which defines the perimeter of a nipple cavity **137**. In some embodiments, the nipple wall **135** has one or more thickened or contoured regions, for example, to create a nipple cavity **137** that is complementary in size and shape to the cartridge **200**, which the nipple assembly **130** is configured to receive. A passage extends through the nipple base **132** providing an opening to the cavity **137** from a distal end of the nipple assembly **130**. As in other embodiments, the nipple is configured for sucking and has a nipple aperture **136** at a proximal end of the nipple **134**, which provides an outlet through which fluid can flow out of the cavity **137**. As shown in the perspective view of FIG. **12**B,

the distal view of FIG. **12**C, and the cross-sectional view of FIG. **12**D, the insertable cartridge **200** is configured to securely couple to the nipple base **132** such that, when engaged, at least a portion of the insertable cartridge **200** is coupled to or positioned within the passage and the cavity **137**. The insertable cartridge **200** of various embodiments securely couples to the nipple base **132** via threading, a snap fit, or other non-permanent attachment means. The insertable cartridge **200** of some embodiments has a proximal cartridge portion, which includes a reservoir **215** configured to hold a fluid and a cartridge aperture **212** at a proximal tip of the cartridge **200**. The insertable cartridge **200** of some embodiments also has a distal cartridge portion, which includes a cap **220** and a pump **222**. In the embodiment of FIGS. **12**A-**12**D, the pump **222** is not a separate element, but rather forms a portion of the cap **220**. The pump **222** of the illustrated embodiment is a compressible pump configured to be squeezed and non-permanently deformed, for example, between the fingers of a caregiver. In other embodiments, other pump designs may be used, such as for example, a syringe plunger.

When the insertable cartridge **200** is engaged with the nipple assembly **130**, the pacifier system **1200** is configured to expel a fluid from the reservoir **215** through the cartridge aperture **212** and out of the nipple assembly **130** through the nipple aperture **136** at least in response to the pump **222** being actuated. In some embodiments, fluid may also be expelled from the reservoir **215** and out the cartridge aperture **212** and the nipple aperture **136** in response to the nipple **134** being sucked. While the cartridge depicted in FIG. **12**A has the depicted shape and design, other shapes and designs are contemplated. For example, rather than a pointed tip at aperture **212**, the end of the cartridge can be round, for example. In some embodiments, the proximal end of the cartridge **220**, when fully inserted into the nipple assembly, contacts an inner proximal end of the nipple or comes very close to contacting a proximal end of the nipple, for example. In one embodiment (not shown), the cartridge is shaped as a syringe body. In such an embodiment, the pump is formed of a plunger, which is configured to be depressed down into the syringe body. In various embodiments, the insertable cartridge **200** may be removed from the apparatus **100** when no longer in use, allowing an individual to continue sucking on the nipple assembly **130**. In some embodiments, the cartridge **200** is disposable and configured for a single use. In other embodiments, the cartridge **200** may be reusable and have, for example, a removable cap **220**, which a caregiver can remove to fill the cartridge **200** with an amount of fluid.

An additional embodiment of a pacifier system is depicted in FIGS. **13**A-**13**C. The pacifier system **1300** includes a pacifier apparatus in the form of a nipple assembly **130**, and additionally, a cartridge **300**. The nipple assembly **130** includes a nipple **134** and a nipple base **132**.

The pacifier system embodiments formed from a pacifier apparatus and a cartridge, such as, for example, the embodiments depicted in FIGS. **12**A-**13**C may be packaged and sold as an interchangeable kit, for example. In one embodiment, the kit includes a plurality of insertable cartridges, for example cartridges **200** or **300**, with each cartridge containing a predetermined volume of a predetermined fluid. Each cartridge within the kit may be configured for a single use. In some embodiments, the kit also includes one or more pacifier apparatuses having some or all of the characteristics of the above-described nipple assembly **130**. The nipple assembly **130** embodiments described herein may be adapted for one-time use or they may be reusable. The nipple assembly **130** of various embodiments is configured to couple to a plurality of cartridges individually, and interchangeably. In addition or alternatively, as described in more detail below, the nipple assembly **130** may be configured to couple to more than one cartridge at a time. For example, one cartridge may be prefilled with sucrose, while the second cartridge is prefilled with a medicament. In some embodiments, the nipple assembly **130** is configured to couple to cartridges having reservoirs of varying sizes intended to hold varying amounts of fluid.

The nipple assembly **130** of FIGS. **13**A-**13**C is depicted in FIGS. **14**A-**14**D in more detail. As in other embodiments, the nipple **134** extends proximally from the nipple base **132** and the shape of the nipple **134** is defined, at least in part, by a contoured nipple wall **135**. In the depicted embodiment, the nipple wall **134** defines the perimeter of a nipple cavity **137**. In some embodiments, and as shown in FIGS. **14**A-**14**D, a receiving tube **160** is disposed within the nipple **134**, for example, within the nipple cavity **137**. In some embodiments, a plurality of receiving tubes may be disposed within the nipple cavity **137**. In various embodiments, the one or more receiving tubes **160** are fixedly attached to, or formed in connection with, a proximal, inner portion of the nipple wall **135**. In some embodiments, the one or more receiving tubes **160** are held in place, at least in part, by one or more support struts **162**; in other embodiments, no support struts **162** are present. Additionally or alternatively, in some embodiments, the one or more receiving tubes **160** are supported, at least in part, by one or more regions of thickened nipple wall **135**, which contact the receiving tube **160** within the nipple cavity **137** and/or in the passage of the nipple base **132**.

In other embodiments, such as, for example, the nipple assembly **130** embodiment of FIGS. **15**A-**15**D, the nipple wall **135** has one or more thickened regions, which partially fill in a portion of the nipple **134** such that an inner portion of the nipple wall **135** defines a lumen. In such embodiments, this lumen forms the receiving tube **160**. In such embodiments, the thickness and diameter of the nipple wall **135** may be constructed to prevent the nipple **134** from collapsing in the absence of support struts **162**. In some embodiments, the material and thickness of the nipple wall **135** are selected such that applying a sucking force to the nipple **134** can cause the receiving tube **160** to non-permanently deform and contract radially inward toward a central axis **158**. In some embodiments, the material and thickness of the nipple wall **135** are selected such that an average sucking force of a child can cause a diameter of the receiving tube **160** to narrow at least 1% to 90%, 95%, 96%, 97%, 98%, or 99%, or any sub-range or value therebetween. In some embodiments, a region of the nipple wall **135** may be thinner than the surrounding nipple wall **135** such that the region is more prone to contraction around the receiving tube **160** at that region. In some embodiments, the receiving tube **160** may be manufactured in a contracted state, and a pressure force, such as a syringe or cartridge expelling a fluid inside the receiving tube **160**, may cause a diameter of the receiving tube **160** to expand radially outward.

In various embodiments, such as, for example, the nipple assembly **130** embodiments of FIGS. **14**A-**14**D and **15**A-**15**D, the receiving tube **160** extends through the nipple **134**, and optionally, into the passage of the nipple base **132**, and optionally, distally beyond the distal face **131**. In various embodiments, the receiving tube **160** can be accessed from a distal side of the nipple assembly **130**, and the receiving tube **160** is sized and configured to receive a cartridge **300** from the distal side of the nipple assembly **130**. In some

embodiments, the receiving tube **160** is uniform in shape; in other embodiments, it includes one or more fitted features, such as, for example, an expanded distal tube portion **164**, configured to securely receive a portion of the cartridge **300** or a portion of a medical instrument. For example, in some embodiments, the expanded distal tube portion **164** is configured to receive and couple to a cartridge spout (for example, the cartridge spout **320** of FIGS. **16**A-**16**F) such that the cartridge spout **320** terminates within the expanded distal tube portion **164** and fills all or substantially all of the expanded distal tube portion **164**.

In other embodiments, the receiving tube **160** includes three distinct portions, for example, an expanded distal tube portion **164**, a medial tube portion **163**, and a proximal tube portion **162** (see, for example, FIG. **23**B). In some such embodiments, the medial tube portion **163** has a smaller diameter than the expanded distal tube portion **164**, and the proximal tube portion **162** has a smaller diameter than the medial tube portion **163**. In some embodiments, for example, the embodiment depicted in FIGS. **23**A-**23**B, the medial tube portion **163** is tapered so as to funnel fluid from a cartridge spout **320** or other fluid-delivering instrument within the expanded distal tube portion **164** to the narrower proximal tube portion **162**. In some embodiments, the gradual or progressive narrowing of the receiving tube **160** helps regulate and control fluid flow. In some embodiments, the gradual or progressive narrowing of the receiving tube **160** is designed to funnel fluid toward the nipple aperture **136** to facilitate the extrusion of all fluid from the receiving tube **160**. Such a design may prevent fluid from getting stuck within the nipple assembly **130**; that is, such a design may eliminate or minimize dead space. The receiving tube may have any suitable length and diameter. For example, the length may be selected to ensure the receiving tube **160** extends the length of the nipple, through the passage of the nipple base, and at least slightly beyond the distal end of the nipple base. For example, the receiving tube may extend 1 mm to 10 cm beyond the distal end of the nipple base. In some embodiments, the receiving tube is sized and shaped to contain a volume of fluid between 0.01 cc's and 0.5 cc's. The receiving tube **160** of some embodiments has an inner diameter between 0.01 mm and 12.0 mm, and preferably between 0.07 mm and 7.0 mm, and the inner diameter may include any sub-range or individual value therebetween. The selected diameter of the receiving tube **160** may depend on the size of the healthcare accessory to which the receiving tube **160** is configured to couple.

In several embodiments, the receiving tube **160** of the nipple assembly **130** is configured to couple, either directly or indirectly, to various accessories, making each of these nipple assembly **130** embodiments a versatile tool for administering fluid and/or orally-administered medical instruments to young, infirmed, or disabled populations. As non-limiting examples, in some embodiments, the nipple assembly **130** is configured to couple to luer lock syringes and enteral feeding syringes of various geometries and to extrusions such as extrusion tubing connected to powered and non-powered devices. In some embodiments, the nipple assembly **130** is configured to couple to intra-esophageal catheters, imaging scopes, intubation tubes, transitional feeding attachments, and other orally-delivered medical instrumentation. As shown, for example, in FIG. **15**D, some embodiments of the nipple assembly **130** have a recessed portion **166** within a passage of the nipple base **132** between the inner receiving tube **160** and the walls of the nipple base **132**. The recessed portion **166** of some embodiments is designed to allow enteral feeding syringes or other instrumentation to couple to the receiving tube **160**. Further, in some embodiments, the recessed portion **166** allows for any medication or fluid that may have leaked from a cartridge during insertion into the receiving tube **160** to be quickly and cleanly retrieved. The recessed portion **166** of various embodiments may be of any suitable shape and size, and the walls defining the recessed portion **166** may be positioned at any desirable angle.

The nipple assembly **130** embodiments depicted in FIGS. **14**A-**15**D also have a handle **116** extending from the base **132** for easy insertion and removal of the nipple assembly **130** by a healthcare provider, for example, from the mouth of an infant and/or patient. As in other embodiments, the nipple **134** is configured for sucking and has a nipple aperture **136** at a proximal end of the nipple **134**, which provides an outlet through which fluid can flow out of the cavity **137**.

FIGS. **16**A-**16**F depict various views of the cartridge **300** embodiment shown in the pacifier system **1300** of FIGS. **13**A-**13**C. The cartridge **300** includes a cartridge body **310** defining a reservoir configured to house a fluid, such as, for example, a medicament, nutritional supplement, or analgesic. The cartridge **300** also includes a proximal cartridge spout **320** configured to fit within the receiving tube **160** of the nipple assembly **130**. In some embodiments, at least a portion of the cartridge body **310** is flexible and/or deformable, for example, to allow a healthcare provider to squeeze the cartridge body **310** to urge fluid out of the reservoir, through the spout **320**, out a cartridge aperture **330**, and into the receiving tube **160** of the nipple assembly **130**.

In some embodiments, the cartridge **300** is prefilled with a pre-measured dose of a liquid. The size of the reservoir, and therefore, the surrounding cartridge body **310**, may vary depending on the amount of liquid provided within the cartridge **300**. In some embodiments, the cartridge **300** contains 0.01 mL to 10.0 mL of liquid, or any sub-range or individual value therebetween. For example, in some such embodiments, the cartridge **300** contains 0.1 mL to 5.0 mL of liquid. In one non-limiting example, the cartridge **300** is sold prefilled with 2.0 mL of liquid.

As shown in FIGS. **16**A-**16**C, before use, some embodiments of a cartridge **300** include a cartridge seal **340**. In such embodiments, the cartridge seal **340** prevents fluid from leaking out of the cartridge spout **320** prior to use. In some embodiments, the cartridge seal **340** also acts as a hermetic seal, maintaining a sterile environment within the spout **320** and reservoir of the cartridge **300** prior to use. In some embodiments, the seal **340** can be fully torn off, cut off, or otherwise removed by a user prior to use. The connection between the seal **340** and the cartridge **300** of some embodiments is perforated or indented, for example, to facilitate breakage of the seal **340** from the cartridge **300**. FIGS. **16**D-**16**F provide views of the cartridge **300** with the cartridge seal **340** fully removed. In other embodiments, only a proximal portion of the seal **340** is configured to be broken off and detached from the cartridge spout **320** so as to expose the cartridge aperture **330**. In some such embodiments, the seal **340** is configured to flex and bend at one or more locations, for example, at a perforation line located on the seal **340** between the detachable portion and a permanently attached portion, thereby allowing the proximal portion of the seal **340** to be broken and moved out of the way while maintaining its attachment to the cartridge body **310**.

In some embodiments, a tab **350** remains attached to a distal end of the cartridge body **310** after the seal **340** is torn.

The tab **350** of some embodiments acts as a handle, facilitating cartridge's **300** insertion into, and removal from the nipple assembly **130**.

In some embodiments of the cartridge **300**, at least a portion of the cartridge body **310** is flexible and deformable. In some embodiments a significant portion of the body **310** is deformable, for example, at least the entire bulbous portion. In some embodiments, the cartridge body **310** allows for repeatable actuation of a substance, for example a fluid, with all or some of the cartridge body **310** non-permanently deforming with each actuation. In some embodiments, two or more recessed finger gripping portions **360** are provided to facilitate gripping; in some such embodiments, the finger gripping portions **360** are less flexible than the bulbous portion, so as to limit unintentional expulsion of fluid during insertion or removal of the cartridge **300** from a pacifier apparatus. Additionally, in some embodiments, the gripping portion **360** has a plurality of defined edges, which create tension and shape memory within the cartridge body **310**, such that following an actuation of the cartridge body **310**, the cartridge body **310** will return to its original position. In various embodiments, pressing on a portion of the cartridge body **310** actuates the cartridge **300**, causing the liquid stored inside the reservoir of the cartridge **300** to flow through the cartridge aperture **330** and out the nipple aperture **136**. Additionally or alternatively, in some embodiments, the cartridge body **310** may deform from negative pressure created when an infant or other individual sucks on the nipple **134** of the attached nipple assembly **130**. Alternatively, in embodiments not shown, the cartridge body **310** may deform permanently; in some such embodiments, the deformation may serve as a visual indicator to a user that a liquid or substance has been expelled through the cartridge aperture **330**.

In various embodiments, the spout **320** is sized and shaped to fit securely within the receiving tube **160** of a nipple assembly **130**. In some embodiments, the spout **320** has an outer diameter between 0.01 mm and 12.0 mm, and the spout diameter may include any sub-range or individual value therebetween. In some embodiments, the diameter of the spout **320** is between 0.06 mm and 6.0 mm. In some embodiments, the diameter of the spout **320** is uniform. In other embodiments, the spout **320** is tapered such that the spout **320** narrows in a proximal direction; in such embodiments, both the largest outer diameter of the spout **320** and the smallest outer diameter of the spout **320** are within the ranges provided above. In various embodiments of the nipple assembly **130**, the diameter of the receiving tube **160** is slightly larger than the cartridge spout diameters to which it couples, such that at least a portion of an inner wall of the receiving tube **160** is in contact with at least a portion of an outer wall of the spout **320**.

In various embodiments, the height and diameter dimensions of the cartridge **300** are selected so as not to pose a choke hazard to young children. For example, in some embodiments, the diameter of the cartridge **300** is at least 1.25 inches. Additionally or alternatively, in some embodiments, the height of the cartridge **300** is at least 2.25 inches. As shown in FIGS. **16A-16F**, in some embodiments, the cartridge seal **340** runs at least the length or substantially the length of the cartridge **300** such that, when detached to open the cartridge aperture **330**, no aspect of the broken seal **340** poses a choking risk. Accordingly, the cartridge **300** of some embodiments is formed such that, when separated, both the seal **340** and the remainder of the cartridge **300** independently conform to choke hazard regulations. For example, when detached, the cartridge seal **340** of some embodiments also has a diameter or width of at least 1.25 inches and/or a height of at least 2.25 inches. In one non-limiting example, the length of the cartridge **300** from a distal tip of the tab **350** to the proximal tip of the cartridge aperture **330** is approximately 2.5 inches; the length of the removable seal **340** at its longest location is approximately 3.1 inches; and the length of the pacifier apparatus **100** with the cartridge **300** securely positioned within the nipple assembly **130** is approximately 3.3 inches. In another embodiment, the length of the cartridge **300** and the length of the seal **340** is 2.25 inches, 5 inches, or any value therebetween. In another embodiment, the diameter or width of the cartridge **300** and the diameter or width of the seal **340** is 1.25 inches, 3 inches, or any value therebetween, for example, 1.5 inches or about 1.5 inches. In other embodiments, other dimensions are selected. In some embodiments, the seal **340** is not fully detachable from the cartridge **300** but rather is permanently attached to the cartridge **300** at one or more sites remote from the cartridge aperture **330**. In some such embodiments, the portion of the seal **340** that is moveable may be sized to pass choke test standards. In other such embodiments, the moveable portion of the seal may have a maximum length smaller than 2.25 inches and a maximum width smaller than 1.25 inches. In some embodiments in which the seal **340** is not fully detachable, the seal **340** is formed of a material having sufficient strength to withstand considerable force without full separation from the cartridge **300**. In various embodiments, both the cartridge **300** and the seal **340** are each configured to withstand considerable force without failing. Failure may include cracking, breaking, separation of a portion configured to be permanently coupled, or deforming to a shape that would prevent the cartridge **300** or the seal **340** from passing choke test standards. For example, in some embodiments, the seal **340** and the cartridge **300** are able to withstand at least 0.5 pounds, 20 pounds, or any value therebetween of force, such as torque or tension, without failing. In one embodiment, the seal **340** and the cartridge **300** are each able to withstand at least 1 pound of force without failing; in another embodiment, the seal **340** and the cartridge **300** are able to withstand at least 5 pounds of force without failing. In some embodiments, any or all of the cartridge **300** components are formed of a plastic, silicone, rubber, other polymer of polymer composite, or any other suitable material.

While the cartridge **300** of various embodiments may be coupled to a nipple assembly **130** as described herein to form a complete pacifier apparatus or system, the cartridge **300** of some embodiments may additionally or alternatively be used independently to administer fluids to individuals. For example, the systems of hermetically sealed cartridges filled with liquid described herein may be positioned directly into an individual's mouth. In use, an individual may suck directly from the cartridge aperture **330** or the cartridge **300** may be squeezed such that the liquid is expelled from the cartridge aperture **330** directly onto the inner cheek or the tongue of an individual.

FIGS. **17A-17E** depict various views of a nipple assembly **130** embodiment configured for use with a cartridge, such as, for example, the cartridge of FIGS. **16A-16F**. As shown in the various views, the nipple assembly **130** of the present embodiment includes a plug **170** and a strap **180**. The strap **180** functions to secure the plug **170** to the nipple assembly **130**. In some embodiments, the strap **180** is flexible and may be rounded, flat, or any other suitable shape or configuration. In some embodiments, the strap **180** has a first end attached to the nipple base **132** and a second end attached to the plug **170**. In some embodiments, the plug **170** has a first portion

172 with ribs, depressions, traction pads, or other features configured to facilitate gripping of the plug 170 by a caregiver. In other embodiments, ribs, depressions, or other traction features may be formed or disposed on the strap 180. The plug 170 of some embodiments has a lateral portion 174 sized and configured to securely fit within a portion of the receiving tube 160. The plug 170 is provided for insertion into a distal end of the receiving tube 160 when no cartridge 300 is secured within the receiving tube 160. When the lateral portion 174 of the plug 170 is placed within the distal end of the receiving tube 160, the plug 170 is configured to fully or substantially occlude the flow of air into the receiving tube 160 from the distal end. In some embodiments, the plug 170 functions to minimize a fluid-receiving individual's ingestion of air through the pacifier apparatus. Additionally, some embodiments of the plug 170 include a medial portion 176 sized and configured to securely fit within a through-hole 103 of the nipple base 132. Such a configuration allows the plug to be placed into a through-hole 103 and out of the way of the user when a cartridge 300 is in position within the receiving tube 160. In other embodiments, the entirety of the plug 170 or a substantial portion of the plug 170 fits securely within both the receiving tube 160 and one or more through-holes 103.

FIG. 18 depicts an additional embodiment of a pacifier apparatus in the form of a nipple assembly 130 configured for use with a cartridge, such as, the cartridge of FIGS. 16A-16F. FIG. 18 depicts three non-limiting examples of possible placements of the plug 170 and the strap 180 in relation to the nipple base 132.

An additional embodiment of a pacifier apparatus in the form of a nipple assembly 130 is provided in FIG. 22. The depicted nipple assembly 130 of the present embodiment includes a valve 182. A cartridge 300, medical instrumentation, or a connector may couple to the valve 182. In some embodiments, the valve 182 functions to occlude the receiving tube 160 in order to prevent ingestion of air by an individual sucking on the nipple 134 when no cartridge 300 or similar apparatus is coupled to the receiving tube 160. In some embodiments, the valve 182 is provided in addition to a strap 180 with a plug 170. In other embodiments, the valve 182 eliminates the need for the plug 170 and the strap 180. In some embodiments, the valve 182 includes a connector portion, such as, for example, valve threads 184, which may be located external or internal to the receiving tube 160. The valve 182 of various embodiments also includes a fluid occluding portion internally disposed within the receiving tube 160. In some embodiments, the fluid occluding portion of the valve 182 is positioned within the expanded distal portion 164, for example, at the proximal end of the expanded distal portion 164. In other embodiments, the fluid occluding portion of the valve 182 is positioned within the medial tube portion 163 or the proximal tube portion 162. The fluid occluding portion of the valve 182 is configured to transition from a closed state to an open state when acted upon by a sufficient force. For example, the valve 182 of FIG. 22 remains in a closed state until acted upon by a force such as expulsion of fluid from the cartridge 300. In other embodiments, the valve 182 is positioned to open when a cartridge 300 is inserted into the receiving tube 160. The valve 182, in some embodiments, is configured to transition from a closed state to an open state when a pressure greater than 2 kilopascals (kPa) is acted on it. In other embodiments, the valve 182 transitions to an open state when a pressure greater than 44 kPa acts on it. In still other embodiments, the minimum pressure needed to transition the valve from a closed state to an open state is an individual value between 2 kPa and 44 kPa, for example, 5 kPa, 10 kPa, 15 kPa, 20 kPa, 25 kPa, 30 kPa, 35 kPa, or 40 kPa. Additionally or alternatively, the valve 182, in some embodiments, is designed to withstand a minimum negative pressure of 200 mmHg without transitioning out of the closed state. Such a pressure may, for example, be exerted by the sucking of an aged one- to thirty-day post-partum infant.

The valve 182 of some embodiments is formed of a material or composite of materials selected from the group consisting of: silicone, rubber, plastic, and other polymers. In other embodiments, any other suitable material may be used. In some embodiments, the valve 182 has an internal diameter taper ratio between 0.140" and 0.300", while the valve threading 184 has an outside diameter between 0.200" and 0.500". The valve 182 may be molded into the receiving tube 160. In some embodiments, the valve 182 replaces the expanded distal tube portion 164. In other embodiments, the valve 182 may be overmolded to the receiving tube 160, for example, using materials and polymers known to withstand greater than 300° melting temperatures. In yet other embodiments, the valve 182 may be fixedly attached to the receiving tube 160 by gluing, ultrasonically welding and/or through other adhesive means. In another embodiment, manufacturing a valve 182 within the receiving tube 160 includes forming a valve 182, separately forming a nipple assembly 130 having a receiving tube 160 with an expanded distal tube portion 164 molded to fixedly retain the valve 182, and upon demolding of the nipple assembly 130, promptly placing the valve 182 within the expanded distal tube portion 164. As the molded polymers or other materials forming the nipple assembly 130 cool, they contract and fixedly secure around and upon the valve 182. The valve 182 of some embodiments is constructed to withstand separation from the receiving tube 160 at least when a tension force up to 10 lbs is exerted on it in any direction from the nipple assembly 130.

The valve 182 and valve threads 184 are designed to couple to a variety of specialty syringes and connectors, such as those found in neonatal feeding syringes and syringe extenders. In some embodiments not shown, the valve 182 may connect to such devices without the valve threads 184 but through a slip-fit, snap fit, friction fit, or other coupling means. In some embodiments, the valve 182 is sized and shaped to prevent coupling with traditional luer lock tapered syringes or with syringes of certain sizes. In one such embodiment, the valve 182 is molded such that the diameter of the valve threads 184 has a size and shape that enables coupling to oral syringes but not luer lock syringes. For example, in one embodiment, the valve 182 with the valve threads 184 has an outer diameter between 0.20" and 0.50", which prevents traditional luer lock designs from coupling. Such a safety feature may be helpful in a clinical setting to reduce errors; specifically, such a feature may help ensure that the nipple apparatus 130 is only coupled to devices intended for oral administration, such as oral syringes, and not intravenous syringes.

FIG. 23A illustrates one embodiment of a system for administering fluids, which includes characteristics to both control, and direct the angle of, fluid flow. Such an embodiment may be advantageous in light of the fact that premature infants and neonates are sensitive to rates of fluid flow. In the depicted embodiment, a receiving tube 160 is fixedly disposed within the interior of a nipple 134 and extends proximally to the nipple aperture 136. When a cartridge 300 is not coupled to the receiving tube 160, the plug 170 on the strap 180 may couple to the receiving tube 160 and block the inlet to the receiving tube 160, allowing the nipple apparatus

130 to act as a soother while preventing air ingestion. The plug 170 of some embodiments is also configured to securely fit within a through-hole 103 within the distal face of the nipple base 132 when the receiving tube 160 is occupied.

In some embodiments of the nipple assembly 130, for example, the nipple assembly 130 of FIG. 23A and FIG. 23B, the receiving tube 160 is disposed within the nipple cavity 137 offset from a central axis 158. The nipple aperture 136 is also offset from the central axis 158. Advantageously, in such configurations, dispensed and/or ingested fluid exits the nipple aperture 136 offset from a central axis 158, thereby minimizing unexpected direct expulsions of fluid into the mouth of a user, and thus, minimizing unwanted physiologic reactions such as choking and/or a gag reflex. Furthermore, such a configuration may be advantageous because hospital protocols for sucrose dispensing increasingly call for sucrose to be administered toward an infant's cheek or buccal surface. Additionally, some premature babies require a dextrose gel to be applied inside the infant's cheek to control hypoglycemia or low blood sugar levels. The disclosed embodiment may address these needs by allowing for fluid and/or gel delivery at a desired angle and orientation within an infant's oral cavity. In some embodiments, the nipple aperture 136 may be disposed on the proximal/bulbous end of the nipple offset from the central axis 158 of the nipple assembly 130 by 1° to 120°, for example, by 10°, 90°, or any value therebetween. In some such embodiments, the receiving tube 160 is laterally affixed to an inner side of the nipple wall 135. In some embodiments, the receiving tube 160 is at least partially defined by an inner side of the nipple wall 135.

In some embodiments, the nipple cavity 137 is hollow; in the alternative, to create a nipple assembly 130 having a greater density and/or improved structural integrity, some or all of the nipple cavity 137 may be filled with the same material that forms the nipple wall 135. In some embodiments, a plurality of receiving tubes 160 are disposed within the nipple cavity 137.

FIGS. 19A-19E illustrate an example of one embodiment of a packaging unit for the pacifier apparatuses and/or nipple assemblies described herein. In the perspective view of FIG. 19A, the packaging unit includes a shell 500 having a distal shell member 501, a proximal shell member 502, and an attachment element 503 configured to detachably connect the distal shell member 501 and the proximal shell member 502. As shown in the exploded view of FIG. 19B and the perspective view of the proximal shell member provided in FIG. 19C, the shell 500 of some embodiments has a plurality of anchor arms 506 extending from an inner surface of the shell 500 into an interior of the shell 500. The plurality of anchor arms 506 are configured to secure any of the pacifier apparatuses described herein. Reference will be made to the pacifier apparatus 100 of FIGS. 9A-9C as a non-limiting example only. In some embodiments, the plurality of anchor arms 506 secure the pacifier apparatus 100 in a stable position inside the shell 500 by engaging with the one or more through-holes 103 located in the nipple base 132 or simply by holding the apparatus in a non-movable position, for example. Such a position of engagement is illustrated in the cross-sectional view of FIG. 19E. In some embodiments, such as the one of FIGS. 19A-19E, the attachment element 503 includes a pull seal 504 configured to wrap substantially around a circumference of the shell 500 and a pull tab 505 affixed to an end of the pull seal 504. The pull seal 504 fixedly couples the distal shell member 501 to the proximal shell member 502 until the pull-tab 505 is pulled and the pull seal 504 is removed. The pull seal 504 of FIGS. 19A and 19B can be attached to a proximal end of the distal shell member 501 and a distal end of the proximal shell member 502, for example, via a perforated connection. Alternatively, in some embodiments, the attachment element 503 and pull seal 505 are built into one or both of the distal or proximal shell member. In some embodiments, the distal shell member and proximal shell member each include a portion of the attachment element; for example, in some embodiments, each shell member has a ridge, groove, threading or the like, which couples one portion of the attachment element to the other portion of the attachment element 503. In various embodiments, the attachment element 503 keeps the shell 500 hermetically sealed such that the sterility of the apparatus 100 is maintained until the seal is broken prior to use. The packaging unit may additionally include, for example, a double-sided adhesive pad 507, as shown in FIGS. 19B and 19C, or an anchor stub 508, as shown in FIG. 19E, positioned on an inner surface of the proximal shell member 502. The adhesive pad 507, anchor stub 508, or other suitable sealant mechanism is provided for engagement with the nipple aperture 136, for example, in order to prevent fluid from leaking out of the nipple aperture 136 of some embodiments prior to use. In some embodiments, the anchor stub 508 may additionally be used to pierce the nipple wall and initially create the nipple aperture 136 instead of making the nipple aperture 136 manufacture or assembly. In some embodiments, the anchor stub has a sharp, pointed, or jagged end. In other embodiments, it has a rounded or blunt end. The shell as depicted has a spherical or rounded shape. It should be understood that any other shape may be used and all suitable three-dimensional shapes are contemplated, for example, cubic, rectangular, pyramidal, oval, cylindrical, trapezoidal, etc. shapes. In some embodiments, the apparatuses, components (e.g., cartridges), etc. may be packaged in a paper, foil and/or plastic wrapper that can be cut or torn open, or that can be separated, for example, and then thrown away. In some embodiments, the items are vacuum packaged inside the outer wrapper.

In some embodiments, the pacifier apparatus 100 is either sterilized or manufactured under sterile conditions and then packaged into the above-described shell or other packaging unit before any fluid or cartridge is added to the apparatus 100. In such embodiments, a healthcare provider, technician or caregiver, prior to use, would add fluid or attach the cartridge. In some embodiments, fluid or a fluid precursor is added to the cavity 137 of the apparatus 100 before the apparatus is sealed within a sterile packaging unit. In various embodiments containing fluid in the cavity 137, the fluid has a desired or a known volume, composition, and concentration. In one particular embodiment, the fluid may include, for example, about 0.5 to about 4 mL (preferably about 2 mL) of a 24% USP sucrose solution. In other embodiments, different volumes, concentrations, and/or different fluids are provided. In some embodiments, the fluid includes, for example, a probiotic formula, a vitamin formula, a nutritive formula, breast milk, colostrum, sweetened water, an anti-gas solution, or a liquid medication. In order to extend the shelf life or portability of the system, the apparatus 100 of some embodiments is packaged so as to contain a fluid precursor. One such fluid-precursor is, for example, a liquid-filled gel capsule. In such an embodiment, a coating of the liquid-filled gel capsule may be configured to dissolve when subjected to a known environmental trigger in order to release the stored fluid into the cavity 137. Such environmental triggers may include, without limitation, exposure to heat, exposure to light, injection of additional fluid into the

cavity **127**, or physical pressure, for example. Another suitable fluid-precursor may be, for example, powder, such as a crystalline sucrose or a lyophilized solution. The powder within the cavity **127** can have a known amount and/or mass and may be configured to dissolve in water. In other embodiments, other fluid precursors may be used.

A plurality of packaging units, such as those described above, may be packaged together into a kit for shipping and/or sale. One embodiment of a kit is provided in FIGS. **20**A-**20**C. In such an embodiment, a plurality of shells **500** are stacked vertically and horizontally. The relatively spherical shape of each shell **500** allows them to be stacked into "egg" cartons, "egg" crates, or boxes. In another embodiment of a kit, a plurality of apparatuses **100** comprising nipple assemblies **130** of various sizes are packaged together. The nipple assemblies may differ in the size of their respective cavities **137**, the diameter of their respective nipples **134**, and/or the size of their respective nipple apertures **136**. Alternatively or additionally, the volume and/or concentration of fluid stored within the cavity **137** may vary across the plurality of apparatuses **100**. With such a configuration, the kits can be tailored to provide apparatuses **100** suitable for a spectrum of age groups.

The pacifier apparatus of various embodiments can be configured to couple, either directly or indirectly, to various accessories, making it a versatile tool for administering fluid or orally-administered medical instruments to young, infirmed, or disabled populations. For example, in some embodiments, the pacifier apparatus is configured to couple to a breast pump. In some such embodiments, the nipple cavity and the nipple aperture of the pacifier apparatus may be sized for receiving, storing, and dispensing colostrum and/or breast milk in amounts appropriate for neonates born at various gestational ages. Additionally, in some embodiments, the apparatus is configured to universally couple with various breast pump designs. In other embodiments, the apparatus can be configured to couple selectively with one or more breast pump designs, such as, for example, those manufactured by Ameda (e.g., Purely Yours®, Purely Yours Ultra™, etc.), Philips (e.g., AVENT), Bailey Medical (e.g., Nurture III), Evenflo (e.g., SimplyGo™) Hygeia (e.g., EnDeare™, EnJoye™, etc.), Medela (e.g., Pump In Style®, Freestyle®, Symphony®, Lactina®, Swing®, Harmony®, etc.), Simplisse®, or other manufacturer. Such breast pumps can include, for example, a breast shield or flange and a pumping mechanism and may optionally comprise a milk-storing container. The pumping mechanism may include, for example, a manual or electrical pump.

In some embodiments, a system for administering fluid includes, for example, a pacifier apparatus, such as, for example, any of the pacifier apparatus embodiments described previously herein, a breast pump as described in the preceding paragraph, and a connector or a means for connecting the breast pump directly or indirectly to at least a portion of the pacifier apparatus. In embodiments of the system having a direct connection between the breast pump and at least a portion of the pacifier apparatus, the connecting means can include, for example, a threaded connection, a fitted snap connection, or other suitable connection. In one such embodiment, the pacifier apparatus includes a nipple assembly and an insertable cartridge, such as, for example, the apparatus shown in FIGS. **12**A-**12**D. A proximal cartridge portion is configured to removably attach directly to the breast pump such that colostrum and/or breast milk can be dispensed and stored in the reservoir of the cartridge. In another embodiment, the breast pump may removably attach directly to a distal end of a nipple assembly. Such a nipple assembly may be configured to securely attach to a second portion of the pacifier apparatus, which includes a balloon, a rigid member, and/or a pump, once the nipple assembly is removed from the breast pump.

In embodiments having an indirect connection between the breast pump and at least a portion of the pacifier apparatus, the connector or connecting means may include, for example, tubing, piping, a funnel, a blunt tip needle, and/or another conduit for directing the flow of fluids from the breast pump to the pacifier apparatus. A first end of the connector, a connecting mechanism, or a connecting means can be configured to attach, at least indirectly, to an outlet of the pumping mechanism or to an outlet in the milk-storing container. In some embodiments of the system, a second end of the connector, a connecting mechanism, or a connecting means is removably attached to the pacifier apparatus at the site of the nipple aperture. Threading or another coupling element may be present to secure the connector, a connecting mechanism, or a connecting means within the nipple aperture. In some embodiments, such as the apparatus shown in FIG. **22**, a connector or connecting mechanism may attach to the valve **182** and valve threading **184**. In balloon-less pacifier apparatus embodiments, such as, for example, those shown in FIGS. **10**A-**10**C and **11**A-**11**C, the connector, the connecting mechanism, or the connecting means may alternatively attach to the pacifier apparatus at or within an opening in either the nipple base or the pump of the pacifier apparatus.

In another embodiment of the system, the nipple assembly **130** has complementary threading or other securement feature such as a snap or friction fit to couple the nipple assembly **130** to a syringe, such as, for example, a syringe from Acacia Neonatal® syringe line. In one non-limiting example, the nipple assembly **130** has securement features designed to couple the nipple assembly **130** to the NuTrio TwistLok™ enteral syringe. The threading or other securement feature of the nipple assembly **130** may be identical or substantially similar to the securement features of a bottle, jar, or other container of fluid such that the syringe can couple interchangeably to the container and the nipple assembly **130**. In some embodiments, the container is configured to hold 1 to 8 ounces of fluid. In some embodiments, the fluid in the container is a medication, such as an antibiotic, analgesic, numbing solution, or anti-gas solution (e.g., simethicone); in other embodiments, the fluid may be any fluid administered for the promotion of health, such as, a vitamins, probiotics, nutraceuticals, colostrum, breast milk, sugar solutions (e.g., sucrose), juices, electrolytes, vaccines, or nutritional supplements. In some embodiments, the nipple assembly **130**, the syringe, and the container may all be packaged as a kit.

Various embodiments of the pacifier apparatuses are configured to minimize the risk of choking. The pacifier apparatuses of some embodiments have no removable or loose parts. For example, in some embodiments, each pacifier apparatus is molded to have a unitary body design; in other embodiments, all components of the pacifier apparatus are permanently coupled to form a single unit. In some such embodiments, the diameter of the pacifier apparatus **100** at its widest location is at least 1.25 inches, and in some embodiments, the length of the apparatus **100** at its longest location is at least 2.25 inches. In other embodiments, each pacifier apparatus is formed of a separable nipple assembly and a separable cartridge. In some such embodiments, the length and diameter dimensions of the each removable part are selected so as not to pose a choke hazard to young children. For example, in some embodiments, the diameter

of the nipple assembly **130** at its widest location is at least 1.25 inches, and the length of the nipple assembly **130** at its longest location is at least 2.25 inches. Similarly, in some embodiments, the diameter of the cartridge (for example, cartridge **200** or **300**) at its widest location is at least 1.25 inches, and the length of the cartridge at its longest location is at least 2.25 inches.

FIG. **21** illustrates one embodiment of a method for manufacturing some of the apparatuses **100** disclosed above. In the embodiment, a nipple assembly **130** is molded such that it includes, for example: a nipple base **132** having a proximal face **133**, a distal face **131**, and a passage extending through the nipple base **132**; and a nipple **134** extending proximally outward from the proximal face **133** and including a nipple wall **135**, which defines a cavity **137**. A nipple aperture **136** is formed through a proximal end of the nipple wall **135**. The nipple aperture **136** may be formed, for example, by making a slit in the nipple wall **135**, using a gauge needle or other apparatus to puncture a hole into the nipple wall **135**, or using any other suitable means. In some embodiments, a balloon **120** is inserted through the passage of the nipple base **132** and into the cavity **137**. In some such embodiments, at least a proximal end of a rigid member **112** is inserted into a distal mouth **122** of the balloon **120** such that the rigid member **112** may be fixedly coupled directly or indirectly to the passage wall upon insertion. In some embodiments, such as the embodiment of FIG. **15**, the rigid member **112** may be tapered to facilitate insertion into the distal mouth **122** of the balloon **120**. Additionally, the cavity **137** is filled with a specified volume of liquid.

In another embodiment, the method of manufacturing a fluid apparatus, such as any of the apparatus **100** embodiments described above, includes, for example, positioning a distal mouth **122** of a balloon **120** around at least a proximal portion of a rigid member **112** such that an air passage exists between a body **124** of the balloon **120** and a hole **104** located on a distal portion of the rigid member **112** or on a pump **141** coupled to the distal portion of the rigid member **112**. The method also includes, for example, permanently affixing the distal mouth **122** to at least the proximal portion of the rigid member **112**, and vacating air from the air passage to retract the balloon **120** into an undeployed state. A nipple assembly **130** is formed, which includes a nipple base **132** and a nipple **134**. The nipple base **132** includes, for example, a proximal face **133**, a distal face **131**, and a passage extending through the nipple base **132**. The nipple **134** extends proximally outward from the proximal face **133** and comprises a nipple wall **135**, which defines a cavity **137**. The method further may include securely affixing the balloon mouth **122** and at least the proximal portion of the rigid member **112** to a wall **138** of the passage, forming a nipple aperture **136** through a proximal tip of the nipple wall **135**, and vacating air from the cavity **137**. Vacating air from the cavity **137** may include removing (e.g., vacuuming or sucking) air from the cavity **137** through the nipple aperture **136** or expelling air through the nipple aperture **136** by transitioning the balloon **120** into a fully deployed state, for example. At some stage of the method, the cavity **137** also may be filled with a desired volume of liquid. Filling the cavity **137** with a volume of liquid may include, for example, injecting the volume of liquid into the cavity **137** through the nipple aperture **136**. Alternatively, it may include any other suitable method of filling the cavity **137**, such as, for example, squeezing the pump **141**, inserting the nipple aperture **136** into a liquid, releasing the pump **141**, and removing the nipple aperture **136** from the liquid when a desired quantity of the liquid has entered the cavity **137**. The method may additionally include, for example, sealing the nipple aperture **136** and/or the hole **104** temporarily so as to prevent fluid from spilling from the cavity **137**. Any other method of manufacture, which successfully manufactures the apparatus **100** of various embodiments, may be used without departing from the teachings or spirit of the disclosure.

The various methods of manufacturing any of the above-described pacifier apparatuses may be tailored so as to create an age-specific and/or procedure-specific pacifier apparatus. In some embodiments, the apparatuses are designed to control the rate of ingestion of a liquid, such as a medicament or nutritional supplement. For example, before molding or otherwise forming the nipple assembly **130**, it may be advantageous to: determine an average number of sucks performed in a defined length of time by patients of a pre-defined age group; determine a desired length of fluid administration; determine a desired volume of fluid to be administered; calculate an optimum flow rate by dividing the desired volume by the desired length of fluid administration; calculate an optimum volume of fluid expelled per suck by dividing the optimum flow rate by the average number of sucks performed in a defined length of time; and select a desired nipple wall **135** thickness, a desired nipple wall **135** density, a desired cavity **137** volume, a desired nipple aperture **136** size, and/or a desired size of a distal cavity opening **104**, such that an apparatus **100** with these desired characteristics is configured to achieve a desired average pressure change within the cavity **137** during a suck and thereby achieve the optimum volume of fluid expelled per suck. The apparatus **100** can then be formed having the desirable age-specific and/or procedure-specific characteristics mentioned above. In one non-limiting example, a pacifier apparatus **100** is designed for the average infant. In some studies, the average infant sucks on a bottle between 50-90 times per minute, creating a negative pressure which induces liquid to flow from the bottle into the infant's mouth. With a bottle, the sucking pressure achieved by the average infant during nutritive sucking is −87.5±28.5 mm Hg. In some embodiments, it is optimal to create an apparatus that achieves similar pressure values. As described above, the pressure achieved within a pacifier apparatus **100** is dependent on a plurality of factors, including, for example, the material characteristics of the nipple wall **135**, the volume of the liquid, the diameter of the nipple aperture **136**, and where applicable, the diameter of the receiving tube **160**. In some embodiments, various characteristics of the apparatus **100**, including the diameter of the receiving tube **160**, are selected such that a pressure of −144.5 mm Hg to −30.5 mm Hg, and preferably, a pressure of −116 mm Hg to −59 mm Hg, or any sub-range or value therebetween is achieved, when the apparatus **100** is used by an individual sucking at an average rate and average force for an infant.

A method of manufacturing a nipple assembly **130** having a receiving tube **160** is also disclosed. The nipple assembly **130** may include some or all the features described elsewhere herein. In some embodiments, the shape of the nipple assembly **130**, complete with a receiving tube **160**, a nipple aperture **136**, and optionally a valve **182** and/or a plug **170** and strap **180** are formed as a single piece, for example, through molding or 3-D printing. In other embodiments, the nipple aperture **136** and/or the receiving tube **160** are added after the nipple and nipple base have formed. In some embodiments, the nipple aperture **136** includes, for example, one or more of a valve, a hole, a slit, and a frangible seal. The nipple aperture **136** may be manufactured with an open slit having a length between 0.005" and 0.1". In some embodi-

ments, the slit may be oriented to help control the rate of fluid flow. For example, a slit may be molded in the nipple aperture **136** that is substantially parallel to the orientation of the user's mouth and lips. In another embodiment, the nipple aperture **136** slit may be perpendicular to the orientation of the user's mouth and lips. A slower fluid flow rate is achieved when the slit in the nipple aperture **136** is parallel to the user's mouth. In some embodiments, the proper directionality of the nipple assembly may be determined by the nipple base **132**. For example, the nipple base **132** may be visually marked to indicate proper orientation. In some embodiments, instructions on the nipple base **132** or the packaging indicate that the nipple aperture slit should be substantially parallel to a user's mouth to achieve a relatively slow flow rate and perpendicular to a user's mouth to achieve a faster flow rate.

In some embodiments, a method of administering medicine or fluid to a user includes removing or partially removing a cartridge seal **340** from a cartridge **300** to expose a cartridge spout **320**. The method further includes inserting the spout **320** into the receiving tube **160** of a nipple assembly **130**. To limit unintentional expulsion of the fluid, the cartridge **300** is held by the tab **350** and/or gripping portions **360** during insertion. The cartridge **300** may be twisted, snapped, or otherwise secured into place in the receiving tube **160**. The apparatus is placed into a user's mouth, optionally, with a specific orientation to achieve a particular strength of flow. The fluid may be expelled by sucking on the nipple **136** or actuating the cartridge body **310**.

As noted above, some embodiments relate to methods of using the apparatuses and systems described herein. For example, some embodiments relate to methods of providing comfort, alleviating pain, and/or treating an illness or medical condition. Examples of such situations include, without limitation, circumcision procedures, venipuncture, diagnostic procedures, upset stomach, gas, bowel movements, colds, flu, fever, and the like. The methods can include identifying a patient (e.g., an infant or neonate) and providing an apparatus as described herein to the patient where the device includes a desired fluid substance for the particular condition. For example, for a circumcision or venipuncture, the infant can be given the apparatus filled with a sugar solution, a pain medication (e.g., acetaminophen), etc. at a desired time prior to (e.g., 1-2 minutes prior to the procedure) or at the commencement of the procedure. If the infant is unable or unwilling to suck so as to receive a sufficient amount of the fluid, then the caregiver, doctor, or guardian can actuate the pump to assist in expelling an adequate amount, if the pump is included in the design. The methods can include the use of apparatuses with a measured volume of the particular solution according to the recommended dosage and/or duration of the procedure. The apparatus can be configured to expel a sufficient dosage of the solution over a desired period of time, such as the length of the pre-procedure time period, procedure time period, and/or any post-procedure time period. Examples of solutions include medications, such as antibiotics, analgesics, numbing solutions, anti-gas solutions (e.g., simethicone), vitamins and minerals, colostrum, breast milk, sugar solutions (e.g., sucrose), juices, electrolytes, vaccines, nutrient formulas, etc.

The foregoing description details certain embodiments of the systems, devices, and methods disclosed herein. It will be appreciated, however, that no matter how detailed the foregoing appears in text, the devices and methods can be practiced in many ways. As is also stated above, it should be noted that the use of particular terminology when describing certain features or aspects of the invention should not be taken to imply that the terminology is being re-defined herein to be restricted to including any specific characteristics of the features or aspects of the technology with which that terminology is associated. The scope of the disclosure should therefore be construed in accordance with the appended claims and any equivalents thereof.

It will be appreciated by those skilled in the art that various modifications and changes may be made without departing from the scope of the described technology. Such modifications and changes are intended to fall within the scope of the embodiments, as defined by the appended claims. It will also be appreciated by those of skill in the art that parts included in one embodiment are interchangeable with other embodiments; one or more parts from a depicted embodiment can be included with other depicted embodiments in any combination. For example, any of the various components described herein and/or depicted in the Figures may be combined, interchanged or excluded from other embodiments.

With respect to the use of any plural and/or singular terms herein, those having skill in the art can translate from the plural to the singular and/or from the singular to the plural as is appropriate to the context and/or application. The various singular/plural permutations may be expressly set forth herein for sake of clarity.

It will be understood by those within the art that, in general, terms used herein, and especially in the appended claims are generally intended as "open" terms (e.g., the term "including" should be interpreted as "including but not limited to," the terms "comprising" and "having" should, respectively, be interpreted as "comprising at least" and "having at least," the term "includes" should be interpreted as "includes but is not limited to," etc.). It will be further understood by those within the art that if a specific number of an introduced claim recitation is intended, such an intent will be explicitly recited in the claim, and in the absence of such recitation no such intent is present. For example, as an aid to understanding, the following appended claims may contain usage of the introductory phrases "at least one" and "one or more" to introduce claim recitations. However, the use of such phrases should not be construed to imply that the introduction of a claim recitation by the indefinite articles "a" or "an" limits any particular claim containing such introduced claim recitation to embodiments containing only one such recitation, even when the same claim includes the introductory phrases "one or more" or "at least one" and indefinite articles such as "a" or "an." In general, "a" and/or "an" should be interpreted to mean "at least one" or "one or more"; the same holds true for the use of definite articles used to introduce claim recitations. Furthermore, in those instances where a convention analogous to "at least one of A, B, and C, etc." is used, in general, such a construction is intended in the sense one having skill in the art would understand the convention (e.g., "a system having at least one of A, B, and C" would include but not be limited to systems that have A alone, B alone, C alone, A and B together, A and C together, B and C together, and/or A, B, and C together, etc.). In those instances where a convention analogous to "at least one of A, B, or C, etc." is used, in general such a construction is intended in the sense one having skill in the art would understand the convention (e.g., "a system having at least one of A, B, or C" would include but not be limited to systems that have A alone, B alone, C alone, A and B together, A and C together, B and C together, and/or A, B, and C together, etc.). It will be further understood by those within the art that virtually any disjunctive

word and/or phrase presenting two or more alternative terms, whether in the description, claims, or drawings, should be understood to contemplate the possibilities of including one of the terms, either of the terms, or both terms. For example, the phrase "A or B" will be understood to include the possibilities of "A" or, "B" or "A and B."

Although the technology has been described with reference to embodiments and examples, it should be understood that numerous and various modifications can be made without departing from the spirit of the invention. Accordingly, the technology is limited only by the following claims.

What is claimed is:

1. A fluid dispensing apparatus, comprising:

a cartridge pre-filled with a pre-measured dose of a liquid, the cartridge comprising:

a cartridge body having a distal end and a proximal end and defining a reservoir, and

a cartridge spout formed of an elongated tubular side wall extending proximally from the proximal end of the cartridge body and terminating at an aperture at a proximal tip of the cartridge spout; and

a cartridge seal attached to the proximal tip of the cartridge spout to prevent liquid from leaking from the aperture prior to use, wherein:

the cartridge seal hermetically seals the liquid within the cartridge, the cartridge seal is fully detachable from the cartridge so as to expose the aperture without exposing any portion of the reservoir,

in a first configuration, prior to detaching, the fully detachable cartridge seal extends across the proximal tip of the cartridge spout and along the entire length of the cartridge body from the proximal tip to at least the distal end of the cartridge body, and

in a second configuration, following detachment of the cartridge seal, the cartridge spout extends freely from the cartridge body such that an outer surface of the tubular side wall lacks any contact with any other portion of the cartridge.

2. The fluid dispensing apparatus of claim **1**, wherein a connection between the cartridge seal and the cartridge is perforated or indented to facilitate breakage of the cartridge seal from the cartridge.

3. The fluid dispensing apparatus of claim **1**, further comprising a tab attached to a distal end of the cartridge body, wherein the tab remains attached to the cartridge following removal of the cartridge seal.

4. The fluid dispensing apparatus of claim **3**, wherein the cartridge has a width of at least 1.25 inches or a length of at least 2.25 inches.

5. The fluid dispensing apparatus of claim **4**, wherein the length is measured from a distal tip of the tab to the proximal tip of the cartridge spout.

6. The fluid dispensing apparatus of claim **1**, wherein the cartridge seal and the cartridge each individually have a width of at least 1.25 inches or a length of at least 2.25 inches.

7. The fluid dispensing apparatus of claim **1**, wherein the cartridge seal and the cartridge are each configured to withstand a force of at least 1 lb without failing.

8. The fluid dispensing apparatus of claim **1**, wherein the cartridge comprises an actuation feature configured to expel fluid from the cartridge.

9. The fluid dispensing apparatus of claim **1**, wherein the cartridge body comprises an actuatable bulbous portion.

10. The fluid dispensing apparatus of claim **9**, wherein the cartridge body further comprises a recessed gripping portion forming a distal portion of the reservoir, wherein the recessed gripping portion is less flexible than the actuatable bulbous portion so as to limit unintentional expulsion of fluid when handling the cartridge.

11. The fluid dispensing apparatus of claim **1**, wherein at least a portion of the cartridge body is deformable.

12. The fluid dispensing apparatus of claim **1**, wherein the premeasured dose of liquid comprises 0.01 mL to 10.0 mL of liquid.

13. The fluid dispensing apparatus of claim **1**, wherein the liquid is selected from the group consisting of an antibiotic, an analgesic, a probiotic solution, a numbing solution, an anti-gas solution, vitamins and minerals, colostrum, breast milk, a sugar solution, juice, electrolytes, a vaccine, and a nutrient formula.

14. The fluid dispensing apparatus of claim **1**, wherein the cartridge is formed of one or more polymers or polymer composite materials.

15. The fluid dispensing apparatus of claim **1**, wherein the cartridge spout is formed such that, following detachment of the cartridge seal, the elongated tubular side wall fits securely within a medical instrument.

16. A fluid dispensing apparatus, comprising:

a cartridge pre-filled with a premeasured dose of a liquid, the cartridge comprising:

a cartridge body defining a reservoir, and

a cartridge spout extending proximally from the cartridge body and terminating at an aperture,

wherein the reservoir comprises a gripping element forming a distal portion of the reservoir, the gripping element being less flexible than the remainder of the reservoir so as to limit actuation of the reservoir when gripped;

a cartridge seal attached to a proximal tip of the cartridge spout to prevent liquid from leaking from the aperture prior to use, wherein:

the cartridge seal hermetically seals the liquid within the cartridge,

the cartridge seal is: detachable from the proximal tip of the cartridge spout, permanently coupled to the cartridge at a location distal to and remote from the cartridge spout, and lacking any locations of connection along an elongated tubular side wall defining the cartridge spout, and

a proximal cartridge seal portion positioned proximal to the location of permanent coupling is moveable away from the cartridge aperture once the cartridge seal is detached from the proximal tip of the cartridge spout; and

a tab attached to a distal end of the cartridge body, wherein the tab remains attached to the cartridge following partial removal of the cartridge seal.

17. The fluid dispensing apparatus of claim **16**, wherein a portion of a connection between the cartridge seal and the cartridge is perforated or indented to facilitate breakage of the cartridge seal from a portion of the cartridge.

18. The fluid dispensing apparatus of claim **16**, wherein the cartridge has a width of at least 1.25 inches or a length of at least 2.25 inches.

19. The fluid dispensing apparatus of claim **18**, wherein the length is measured from a distal tip of the tab to the proximal tip of the cartridge seal.

20. The fluid dispensing apparatus of claim **16**, wherein the proximal cartridge seal portion and the cartridge each individually have a width of at least 1.25 inches or a length of at least 2.25 inches.

21. The fluid dispensing apparatus of claim **16**, wherein the cartridge seal and the cartridge are each configured to withstand a force of at least 1 lb without failing.

22. The fluid dispensing apparatus of claim **16**, wherein the cartridge comprises an actuation Feature configured to expel fluid from the cartridge.

23. The fluid dispensing apparatus of claim **16**, wherein the cartridge body comprises an actuatable bulbous portion.

24. The fluid dispensing apparatus of claim **16**, wherein the gripping element comprises a recessed gripping portion.

25. The fluid dispensing apparatus of claim **16**, wherein the premeasured dose of liquid comprises 0.01 mL to 10.0 mL of liquid.

26. The fluid dispensing apparatus of claim **16**, wherein the liquid is selected from the group consisting of: an antibiotic, an analgesic, a probiotic solution, a numbing solution, an anti-gas solution, vitamins and minerals, colostrum, breast milk, a sugar solution, juice, electrolytes, a vaccine, and a nutrient formula.

27. The fluid dispensing apparatus of claim **16**, wherein the cartridge is formed of one or more polymers or polymer composite materials.

28. The fluid dispensing apparatus of claim **16**, wherein the cartridge spout has a circular cross-section with an outer diameter between 0.01 mm and 12.0 mm.

29. The fluid dispensing apparatus of claim **16**, wherein the cartridge spout is formed such that, following detachment of the cartridge seal, the elongated tubular side wall fits securely within a medical instrument.

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